INTERNATIONAL MARITIME ORGANIZATION

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FORMAL SAFETY ASSESSMENT INCLUDING ENVIRONMENTAL INDEXING OF SHIPS

Report of the joint MSC/MEPC Working Group on the Human Element and Formal Safety Assessment

Introduction

1 The joint MSC/MEPC Working Group on the Human Element and Formal Safety Assessment met from 18 to 23 May 2000 under the chairmanship of Mr. R. P. Cazzulo (Italy). Delegations from Barbados, Bulgaria, Canada, China, Cyprus, Denmark, Finland, France, Germany, Greece, India, Jamaica, Japan, Liberia, Norway, Panama, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Singapore, Sweden, Turkey, Ukraine, United Kingdom, United States, and observers from ILO, EC, ICS, ISF, ICFTU, IACS, OCIMF, IMPA, IFSMA, INTERTANKO, IME and ISMA participated.

GENERAL

2 The Maritime Safety Committee, at its sixty-ninth session (11 to 20 May 1998) decided (MSC 69/22, paragraph 13.18) and the Marine Environment Protection Committee, at its forty second session (2 to 6 November 1998), concurred with the decision (MEPC 42/22, paragraph 16.4.2), that the Joint Working Groups on the Human Element (HE) and on Formal Safety Assessment (FSA) should be combined into one Joint MSC/MEPC Working Group on Human Element and Formal Safety Assessment.

Terms of reference

3 The working group was instructed, taking into account comments and proposals made in plenary, to:

Amendments to SOLAS chapter IX and the ISM Code

.1 consider the proposals made to this session by Denmark, Norway and Poland (MSC 72/15/1) and to prepare draft amendments to SOLAS chapter IX and the ISM Code for approval by the plenary, bearing in mind that the amendments should be kept to the bare minimum;

Correspondence Group on Fatigue

.2 review the report of the Correspondence Group on Fatigue (MSC 72/15) and make recommendations in respect of those issues identified in the report as requiring further consideration, including the terms of reference for the Correspondence Group to continue its work intersessionally, if needed;

Human element activities

.3 review the human element activities carried out by the Organization and, on the basis of the document submitted by the United States (MSC 72/15/2), to make appropriate recommendations for consideration by the plenary;

.4 note the information submitted by Japan (MSC 72/INF.9) and, if appropriate, to make recommendations to the plenary accordingly; and

Formal Safety Assessment

.5 further develop amendments to the FSA Interim Guidelines on the basis of the texts contained in annexes 5 to 8 of document MSC 71/WP.15/Add.1 and in the light of the relevant decisions of MSC 71 (document MSC 71/23, paragraphs 14.2 to 14.14), taking also into consideration the comments and proposals made in the documents submitted to the present session (MSC 72/16, MSC 72/16/1, MSC 72/16/2, MSC 72/INF.10 and MSC 72/INF.17);

.6 consider the need for the establishment of a correspondence group to deal with FSA matters and, if so, to prepare draft terms of reference;

.7 consider the outstanding work to be done for FSA and to propose a plan in order to allow the Committee to prioritise its work; and

.8 report to the plenary on Thursday, 25 May 2000.

HUMAN ELEMENT MATTERS

Amendments to SOLAS chapter IX and the ISM Code

4 The group developed draft amendments to the ISM Code and consequential amendments to chapter IX of SOLAS given at annexes 1 and 2. A draft MSC resolution was developed as set out in annex 3. No consequential amendments were made to the Guidelines on the implementation of the ISM Code by Administrations contained in resolution A.788(19). The group invited the Committee to approve the amendments for circulation and possible adoption at MSC 73.

5 The group, taking into account the discussion in plenary, agreed to sub-divide the text of the ISM Code into two parts, namely Part A - Implementation, and Part B - Certification and Verification, without amending the existing numbering of the chapters and paragraphs. The definitions proposed in document MSC 72/15/1 were agreed and the group decided they should apply to both Parts A and B.

6 The group noted the concerns raised by the Russian Federation regarding the new forms of certificates proposed in these draft amendments which may be different from the existing certificates and their concerns about the validity of those certificates that have already been issued. The group recommended that Administrations and port State control officers should continue to accept the existing format and validity of certificates until the date of their renewal. This guidance was included in the draft MSC resolution for adopting the amendments given at annex 3.

7 The group, having considered the proposal made by Venezuela in the plenary to include Spanish as an official language on certificates, noted that this proposal also affected other types of certificates and agreed that the matter should be considered in a broader perspective by the Committee when considering the proposals made by Spanish speaking countries (MSC 72/21/11) under agenda item 21, Work programme.

8 In order to harmonize the issuing of SMCs with other SOLAS certificates, the group amended paragraph 13.7 of the ISM Code (see also annex 2) to include a provision for the issue of an SMC by another Contracting Government at the request of the Administration.

9 In order to clarify the validity of SMCs regarding the endorsement of intermediate and additional verification, the group agreed to add a reference to paragraph 3.2.3 of resolution A. 788 (19) on the relevant form of the SMC certificate.

10 With regard to the proposal to harmonise the ISM audits and certificates with the harmonised system of survey and certification, the group agreed with the discussion in plenary that the present system as set out in resolution A.788(19) should be continued.

11 The group invited the Committees to recommend to Administrations and recognised organizations that verification of SMCs should be carried out when the ship is fully manned, when it is in operation as this may not be the case when the ship is in dry-dock. The group also recognised that the one-year-window period given for intermediate verification should be sufficient for this purpose. This matter could be considered at a future date after adequate experience has been gained following the full implementation of the ISM Code.

12 A number of other issues were also introduced and briefly discussed, including;

.1 increasing the frequency of the intermediate verification of SMC to annually in line with the harmonised system of survey and certification; and

.2 developing criteria for achieving more consistency in the Guidelines on the issue of interim DOCs and SMCs

and the group agreed that these issues should be discussed in the future based on proposals which could be submitted to the Committees by Member Governments.

13 The group noted the opinion of ISMA that guidance should be developed on matters related to non-conformities which go beyond the scope of the safety management systems required by the ISM Code.

Review of the report of the Intersessional Correspondence Group on Fatigue

14 The group considered the report of the Intersessional Correspondence Group on Fatigue (MSC 72/15) and agreed that:

.1 the report provided a very good basis for further consideration of this issue;

.2 the proposed structure for the modules was appropriate for the guidelines being developed, with each module being a self-contained unit;

.3 that module 1 should contain general information on, and fundamental aspects of, the subject of fatigue;

.4 the title of module 2 should be changed to 'Fatigue and the Ratings'

.5 two new modules pertaining to maritime pilots and tugboat personnel should be developed by the Correspondence Group;

.6 for the reasons in paragraph 15.2 above, existing module 8 (containing reference information on fatigue-related issues) should be used as an appendix to all modules and not be numbered separately in order to facilitate the addition of new modules as they are developed;

.7 new modules may be desirable in the future such as those relating to VTS personnel and personnel on mobile offshore drilling units and supply vessels but, due to time constraints, this would not be taken up by the Correspondence Group at this stage; and

.8 the Correspondence Group[1] should continue its work in accordance with the new terms of reference set out at annex 4.

15 The group further agreed that the guidelines being developed would benefit other personnel, including shore-based personnel, who have a role in maritime safety and protection of the marine environment.

16 The group also agreed that the dissemination of the guidelines should be as wide-ranging as possible when finalised by the group and approved by the Committees as an MSC/MEPC circular. In this regard, the group concurred with the view expressed by the ILO representative that the Committees may wish consider the dissemination of these guidelines as a joint ILO/IMO document.

Human element activities

17 The group reviewed the human element activities carried out by the Organization on the basis of information submitted by the United States (MSC 72/15/2) and the goals given in resolution A.850(20). The group prepared a summary report of ongoing human element activities in IMO, as given at annex 5, and recommended that the information should be updated on a regular basis. The group also noted that, in future, it may be necessary to include practical skills and capacities of seafarers as additional human element activities.

18 The group agreed that it was necessary to create a new impetus in the consideration of the human element by the Committees, Sub-Committees and other bodies of the Organization. The group noted that the Fire Protection Sub-Committee had taken into account the human element while undertaking the comprehensive review of SOLAS chapter II-2, which was to be approved at this session of the Committee. To help in addressing the human element at the earliest stages of rule-making, the group recommended that the Committees consider instructing the Sub-Committees to apply the Human Element Analysing Process (HEAP) given in MSC/Circ.878/MEPC/Circ.346 as a matter of priority in their work.

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19 The group also recommended that the Committees instruct the Sub-Committees to provide information on experience gained during application of the HEAP process with a view to further improving of the process.

20 The group noted that consideration of the human element has been taken into account in the FSA guidelines.

21 The group appreciated the efforts made by the United States in establishing an internet database on studies, research and other information related to the human element that could be accessed by Administrations and non-governmental organizations. The group recommended that the Committees invite Member Governments to supplement this database with more information on studies and investigation analyses from the human element point of view.[2]

22 The group noted the need for seafarers to be aware of the contents of various mandatory instruments and appreciated the development of the 'Manual on operational requirements for seafarers' (MSC 72/22/1) pertaining to the IMO requirements that are applicable to them.

23 The group developed a proposed work plan on IMO-related human element activities given at annex 6.

24 The group noted the information submitted by Japan (MSC 72/INF.9) and appreciated the work undertaken on near misses due to the human element. The group recommended that the Committee instructs the NAV Sub-Committee to consider this document in detail at its next session.

FORMAL SAFETY ASSESSMENT

25 The Maritime Safety Committee, at its sixty-eighth session (28 May to 6 June 1997), and the Marine Environment Protection Committee, at its fortieth session (18 to 23 and 25 September 1997), approved the Interim Guidelines for the Application of Formal Safety Assessment (FSA) to the IMO Rule-Making Process. These Guidelines were intended to facilitate trial applications of the FSA process. The Maritime Safety Committee, at its seventy-first session, developed draft amendments to the guidelines (MSC 71/WP.15/Add.1, annexes 5 to 8).

26 The group considered further improvements to the FSA Interim Guidelines (MSC/Circ.829/MEPC/Circ.335) on the basis of the texts contained in annexes 5 to 8 of document MSC 71/WP.15/Add.1 and in the light of relevant decisions of MSC 71 (paragraphs 14.2 to 14.14 of document MSC 71/23) and documents submitted at this session by Norway (MSC 72/16), the United Kingdom (MSC 72/16/1), the United States (MSC 72/16/2) and Japan (MSC 72/INF.17).

27 The group agreed to incorporate in the draft revised FSA guidelines the following:

.1 guidelines on practical application of FSA to the IMO rule-making process (MSC 71/WP.15/Add.1, annex 5);

.2 guidance on the use of experts in the FSA application (MSC 71/WP.15/Add.1, annex 7); and

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[2] http:\\www.uscg.mil/humanelements.

.3 guidance on the use of Human Reliability Analysis (HRA) within Formal Safety Assessment (MSC 71/WP.15/Add.1, annex 8).

28 With regard to the Human Reliability Analysis (HRA), the group agreed this is one possible approach to integrating the Human Element into the FSA. The group also agreed that the flow chart given in figure 1 of document MSC 72/16/2 provided useful information for incorporating both the Human Element and Formal Safety Assessment into the rule-making process and decided to include this figure and a new paragraph on this issue in the draft revised FSA guidelines, given in figure 3 and appendix 2 to annex 7. The group agreed to move the paragraph concerning Human Element from FSA step 1 to chapter 3 on the general methodology.

29 The group further discussed the use of Regulatory Impact Diagrams (RID) taking into account the information given in:

.1 paragraph 5.3 and figure 5 of the FSA Interim Guidelines;

.2 guidance on the use of RID given at annex 6 to MSC 71/WP.15/Add.1; and

.3 document MSC 72/16/1 by the United Kingdom.

30 The group agreed that RID may be used in qualitative terms for assessing the influence of regulations in respect of effective prevention of accidents. However, to be confident about the possible use of this technique, more information on the practical application was needed. In that respect, the group amended the draft FSA guidelines by deleting paragraph 5.3 and included the use of regulatory impact diagrams (RID) as a new appendix to the guidelines, to be considered as a basis for further discussions.

31 The group considered the information submitted by Norway (MSC 72/16) relating to decision parameters including risk acceptance criteria. Whilst appreciating the efforts made by Norway in developing these criteria, the group agreed that this concept would need further considerations, in particular concerning the following:

.1 presentation of absolute figures on risk acceptance could be misinterpreted by the decision makers;

.2 the term ‘risk-evaluation criteria’ should be used instead of ‘risk-acceptance criteria’ in order to prevent misinterpretation;

.3 the application of some risk-evaluation criteria were considered necessary to compare different risk control options, in particular when risks were to be kept as low as reasonably practicable (ALARP); and

.4 the need to gather further information on the application of risk evaluation criteria subject before incorporating this concept into the guidelines.

32 The group agreed that, in light of continuous FSA applications being developed, further improvements to the FSA interim guidelines should be discussed as a matter of priority at its next session. The group also agreed that further improvements to the guidelines should include the integration of the Human Element into the FSA process.

33 The group therefore recommended that the Committees establish an intersessional correspondence group under the co-ordination of Japan[3] with terms of reference set out in annex 8. In order to facilitate the work to be carried out intersessionally, the group developed an amended version of the guidelines (see annex 8) which included the additional appendices referred to in paragraphs 29 and 31 above.

34 The observer from IACS advised the group that, in response to the need for the standardized training package identified in document MSC 71/WP.15/Add.1, paragraph 31, IACS had developed an FSA training package for the establishment of a basic understanding of FSA methodology. The group welcomed an offer from IACS to make the training package available at MSC 74.

35 With regards to the future work programme, the group identified the following outstanding issues on FSA for consideration at its next session:

.1 finalisation of the improved draft revised FSA guidelines for their continuous application and the consequent ending of the period of trial applications;

.2 further integration of the Human Element and FSA into the IMO decision-making process; and

.3 development of risk evaluation criteria with regard to maritime safety and the protection of the marine environment.

36 In order to facilitate the development of risk evaluation criteria for the protection of the marine environment, taking into consideration the desirability of their integration in the "precautionary approach", the Committees were invited to urge Member Governments to include experts on protection of the marine environment in their delegations attending MSC 74.

37 The group welcomed the information submitted by Japan (MSC 72/INF.17) regarding the methods for reducing the number of accident scenarios to be considered in FSA studies. Since this study was related to evacuation of passengers due to fire and smoke risks in accommodation spaces, the group recommended that the Committee instructed the proposed working group on large passenger ship safety to consider this document at MSC 73.

WORK PLAN

38 The group recommended that the Committees approve the following work plan for the future work of the joint MSC/MEPC Working Group on HE and FSA at MSC 74:

Human Element Issues

.1 to consider the outcome of the intersessional correspondence group on fatigue with a view to finalizing the relevant practical guidance for the information of all interested parties;

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.2 to update, on a continuous basis, the list of IMO-related Human Element activities and progress thereon;

.3 to take into consideration comments relevant to the application of the Human Element Analysing Process (HEAP) by Committees and Sub-Committees with a view to the further improvement of this process; and

Formal Safety Assessment

.4 to consider the outcome of the intersessional correspondence group on FSA with a view to finalizing the improved guidelines;

.5 to consider further the integration of the Human Element and the FSA into the IMO rule-making process;

.6 to develop risk evaluation criteria with regard to maritime safety and the protection of the marine environment; and

.7 to develop a training package for the establishment of a basic understanding of the FSA process.

39 In view of the work being undertaken by the two proposed correspondence groups on fatigue and FSA respectively and to allow them sufficient time to complete their work, the group recommended that the Committees should not reconvene the joint MSC/MEPC Working Group on HE and FSA at MSC 73.

Action requested of the Committee

40 The Marine Environment Protection Committee is invited to:

.1 approve the draft amendments to the ISM Code and the consequential amendments to chapter IX of SOLAS for circulation and possible adoption at MSC 73 (paragraph 6 and annexes 1 and 2);

.2 note the draft MSC resolution on the adoption of the draft amendments taking into account the comments of the Russian Federation (paragraph 7 and annex 3);

.3 agree that the intersessional Correspondence Group on Fatigue should continue its work under the co-ordination of the United States with new terms of reference (paragraph 15 and annex 4);

.4 note the summary report of the human element activities within the Organization (paragraph 18 and annex 5);

.5 instruct the Sub-Committees to apply the Human Element Analysing Process (HEAP) to address the human element as a matter of priority in their work (paragraph 19);

.6 instruct the Sub-Committees to provide information on experience gained during the application of the HEAP process with a view to further improvement of the process (paragraph 20);

.7 note the efforts made by the United States to establish an internet database on human element issues and invite Member Governments to supplement this database with more information on studies and investigation analyses from the human element view point (paragraph 22);

.8 note the proposed work plan on IMO Human Element-related activities (paragraph 24 and annex 6);

.9 agree to establish an intersessional correspondence group on FSA, under the co-ordination of Japan, with terms of reference set out in annex 7 (paragraph 34);

.10 note the offer by IACS to present to MSC 74 a training package on the establishment of a basic understanding of FSA methodology (paragraph 35);

.11 urge Member Governments to include experts on protection of the marine environment in their delegations to MSC 74 (paragraph 37);

.12 instruct the proposed working group on large passenger ships' safety to consider document submitted by Japan (MSC 72/INF.17) (paragraph 38);

.13 approve the work plan for the future work of the group (paragraph 39);

.14 agree that the joint MSC/MEPC working group need not be reconvened at MSC 73 (paragraph 40); and

.15 approve the report in general.

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ANNEX 1

DRAFT AMENDMENTS TO THE ISM CODE

1 New titles are added as follows:

.1 Add a new title before chapter 1: "PART A - Implementation"

.2 Add a new title before chapter 13: "PART B - Certification and verification"

2 The following amendments are made to the Code:

.1 Insert the following sentence before paragraph 1.1: Definitions

“These definitions apply both to Parts A and B”

.2 Add the following new definitions to paragraph 1.1:

“1.1.4 *Safety Management System (SMS)* means a structured and documented system enabling Company personnel to implement effectively the Company safety and environmental protection policy.

1.1.5 *Document of Compliance (DOC)* means a document issued to a Company which complies with the requirements of the ISM Code.

1.1.6 S*MC (SMC)* means a document issued to a ship which signifies that the Company and its shipboard management operate in accordance with the approved SMS.

1.1.7 *Objective evidence* means quantitative or qualitative information, records or statements of fact pertaining to safety or to the existence and implementation of an SMS element, which is based on observation, measurement or test and which can be verified.

1.1.8 *Observation* means a statement of fact made during a safety management audit and substantiated by objective evidence.

1.1.9 *Non-conformity* means an observed situation where objective evidence indicates the non-fulfilment of a specified requirement.

1.1.10 *Major non-conformity* means an identifiable deviation which poses a serious threat to the safety of personnel or the ship or a serious risk to the environment which requires immediate corrective action and includes the lack of effective and systematic implementation of a requirement of the ISM.

1.1.11 *Anniversary date* means the day and month of each year which corresponds to the date of expiry of the relevant certificate."

.3 The existing chapter 7 is deleted and replaced by the following:

“7 DEVELOPMENT OF PLANS FOR SHIPBOARD OPERATIONS

The Company should establish procedures for the preparation of plans and instructions, including checklists as appropriate, for key shipboard operations concerning the safety of the ship and the prevention of pollution. The various tasks involved should be defined and assigned to qualified personnel.”

.4 The existing chapter 13 is deleted and replaced by the following:

“13 CERTIFICATION

13.1 The ship should be operated by a Company which has been issued a DOC relevant to that ship.

13.2 A DOC should be issued by the Administration, by an organization recognized by the Administration, or at the request of the Administration by another Contracting Government to the 1974 SOLAS Convention, to any Company complying with the requirements of the ISM Code for a period specified by the Administration which should not exceed five years. Such a document should be accepted as evidence that the Company is capable of complying with the requirements of the Code.

13.3 The DOC is only valid for the ship types explicitly indicated in the document. Such indication should be based on the types of ships on which the initial verification was based. Other ship types should only be added after verification of the Company’s capability to comply with the requirements of this Code applicable to such ship types. In this context, ship types are those referred to in SOLAS chapter IX.

13.4 The validity of a DOC should be subject to annual verification by the Administration, by an organization recognized by the Administration, or at the request of the Administration, by another Contracting Government within three months before or after the anniversary dates.

13.5 The DOC should be withdrawn, by the issuing Administration only, in cases where the periodical verification is not requested or if evidence is found of major non-conformities with this Code. Associated SMCs should also be withdrawn if the DOC is withdrawn.

13.6 A copy of the DOC should be placed on board in order that the master, if so requested, may produce it for verification by the Administration or organizations recognized by the Administration. Such a document is not required to be authenticated or certified.

13.7 The SMC should be issued to a ship for a period, which should not exceed five years, by the Administration or an organization recognized by the Administration or at the request of the Administration by another Contracting Government. The Administration should, when issuing the certificate, verify that the Company and its shipboard management operate in accordance with the approved SMS.

13.8 The validity of the SMC should be subject to at least one intermediate verification by the Administration or an organization recognized by the Administration. If only one intermediate verification is to be carried out, and the period of validity of the SMC is five years, it should take place between the second and third anniversary date of the SMC.

13.9 The SMC should be withdrawn by the Administration in cases where intermediate verification is not requested or in accordance with the provisions of paragraph 13.5 or if there is evidence of major non-conformity with this Code.

13.10 Notwithstanding the requirements of paragraphs 13.2 and 13.7, when the renewal verification is completed within three months before the expiry date of the existing DOC or SMC, the new DOC or SMC should be valid from the date of completion of the renewal verification for a period not exceeding five years from the date of expiry of the existing DOC or SMC."

.5 Insert new chapter 14 as follows:

"14 INTERIM CERTIFICATION

14.1 An interim DOC may be issued to facilitate initial implementation of this Code where a Company is newly established or where new ship types are added to an existing DOC, following verification that the Company has a safety management system that meets the objectives of paragraph 1.2.3 of this Code. Such an interim DOC should be issued for a period not exceeding 12 months by the Administration, by an organization recognized by the Administration, or at the request of the Administration by another Contracting Government. The Administration should require the Company to demonstrate plans to implement a SMS meeting the full requirements of this Code within the period of validity of the interim DOC.

14.2 An Interim SMC may be issued to new ships on delivery and when a Company takes on responsibility for the management of a ship which is new to the Company. Such an interim SMC should be issued for a period not exceeding 6 months by the Administration or an organization recognized by the Administration.

14.3 An Administration may, in special cases, extend the validity of an interim SMC for a further period which should not exceed 6 months from the expiry date.

14.4 Before issuing an interim SMC the Administration should verify that:

.1 the DOC, or the interim DOC, is relevant to the ship concerned;

.2 the SMS provided by the Company for the ship concerned includes key elements of this Code and has been assessed during the audit for issuance of the DOC or demonstrated for issuance of the interim DOC;

.3 the master and officers are familiar with the SMS and the planned arrangements for its implementation;

.4 instructions which have been identified as being essential are provided prior to sailing;

.5 plans for a Company audit of the ship within three months exist; and

.6 relevant information on the SMS has been given in a working language or languages understood by the ship's personnel."

.6 Insert new Chapter 15 as follows:

"15 FORMS OF CERTIFICATES

15.1 The DOC, SMC, interim DOC and interim SMC should be drawn up in the form corresponding to the models given in the appendix to this Code. If the language used is neither English nor French, the text should include a translation into one of these languages.

15.2 The ship type indicated on the DOC and the SMC, as defined in SOLAS chapter IX, may be supplemented by information reflecting the ships operations described in the SMS and the service in which the ship operates."

.7 Insert new Chapter 16 as follows:

"16 VERIFICATION

All verifications required by the provisions of this Code should be carried out in accordance with a procedure acceptable to the Administration, taking into account the guidelines developed by the Organization[4]."

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[4] Refer to Guidelines on implementation of the International Safety Management (ISM) Code by Administrations (resolution A.788(19)).

ANNEX 2

DRAFT AMENDMENTS TO SOLAS CHAPTER IX

1. Add the following text at the end of existing regulation IX/3.1:

   "*For the purpose of this regulation, the requirements of the Code shall be treated as mandatory*."

2. Delete the following words in existing regulation IX/6.2:

   "*Subject to the provisions of paragraph 3 of this regulation*"

3. Delete existing regulation IX/6.3

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ANNEX 3

DRAFT RESOLUTION MSC.[…](73)
(adopted on […2000])

ADOPTION OF AMENDMENTS TO THE INTERNATIONAL CONVENTION FOR THE SAFETY OF LIFE AT SEA (SOLAS), 1974, AS AMENDED AND THE INTERNATIONAL SAFETY MANAGEMENT (ISM) CODE

THE MARITIME SAFETY COMMITTEE**,**

RECALLING Article 28(b) of the Convention on the International Maritime Organization concerning the functions of the Committee,

RECALLING FURTHER article VIII(b) of the International Convention for the Safety of Life at Sea (SOLAS), 1974, hereinafter referred to as “the Convention”, concerning the procedures for amending the Convention and the International Safety Management (ISM) Code, hereinafter referred to as the "ISM Code",

HAVING CONSIDERED, at its [seventy-second/third?] session, amendments to the Convention proposed and circulated in accordance with article VIII(b)(i) thereof,

1. ADOPTS, in accordance with article VIII(b)(iv) of the Convention, amendments to the SOLAS Convention and the ISM Code, the text of which is set out in the annexes to the present resolution;

2. DETERMINES, in accordance with article VIII(b)(vi)(2)(bb) of the Convention, that the amendments set out in the annexes shall be deemed to have been accepted on [1 January 2002] unless, prior to these dates, more than one third of the Contracting Governments to the Convention or Contracting Governments the combined merchant fleets of which constitute not less than 50% of the gross tonnage of the world’s merchant fleet, have notified their objections to the amendments;

3. INVITES Contracting Governments to note that, in accordance with article VIII(b)(vii)(2) of the Convention, the amendments set out in the annexes shall enter into force on [1 July 2002] upon their acceptance in accordance with paragraph 2 above;

4. REQUESTS the Secretary-General, in conformity with article VIII(b)(v) of the Convention, to transmit certified copies of the present resolution and the text of the amendments contained in annex 1 to all Contracting Governments to the Convention;

5. FURTHER REQUESTS the Secretary-General to transmit copies of this resolution and its annex to Members of the Organization, which are not Contracting Governments to the Convention.

6. RECOMMENDS that Member Governments provide guidance to both flag State and port State control officers on the acceptance of existing certificates pertaining to the ISM Code in their present form until their renewal.

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ANNEX 4

DRAFT TERMS OF REFERENCE FOR THE INTERSESSIONAL CORRESPONDENCE GROUP ON FATIGUE

1 To continue the development of practical guidance on fatigue to all relevant parties, taking into account the following:

.1 each module should be self-contained;

.2 module 1 should contain general information on, and fundamental aspects of, the subject of fatigue;

.3 the title of module 2 should be changed to 'Fatigue and the Rating'

.4 existing module 8 should be used as an appendix and not be numbered separately, in order to facilitate the addition of new modules as they are developed;

.5 two new modules pertaining to maritime pilots and tugboat personnel should be developed; and

.6 references to mandatory instruments should be highlighted in an appropriate manner.

2 In addition, case studies and examples should be developed for each module as appropriate and should be highlighted in an appropriate manner.

3 The Correspondence Group should make proposals on the best use of the information contained in the modules and ensure that the information is presented in an 'user friendly' format.

4 The Correspondence Group should submit its report containing the draft guidelines to the Committee for approval at its seventy-fourth session.

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ANNEX 5

SUMMARY ON IMO-RELATED HUMAN ELEMENT ACTIVITIES AND PROGRESS THEREON

	ACTIVITY	DOCUMENT	STATUS	SUPPORTED GOAL (From A.850(20))	COMMENTS
1.	Instruction to Sub-Committees containing the following: - Review the adequacy of requirements and recommendations for equipment and operating manuals and operational guidelines on board ships - Consider the simplification and standardization of terminology in operating manuals and symbols and signs used on board ships - Identify words and phrases used in IMO instruments relating to human performance criteria and determine the extent to which they can be more specifically defined - Give appropriate consideration to a list of questions on subjects relating to human factors - Report to the Committees on their progress	MSC 65/25, Annex 29	Ongoing	Goals (a) and (b)	The MSC/MEPC JWG Group received comments and replies from several Sub-Committees (as of MSC 69). Activities were listed in a report to MSC 69 (MSC 69/13, annex 3).

	ACTIVITY	DOCUMENT	STATUS	SUPPORTED GOAL (From A.850(20))	COMMENTS
2.	Creation of an intersessional correspondence group with the following terms of reference:				
	2.1 to develop a draft strategic plan for addressing HE which will include recommended tasks and deadlines	A.850(20) MSC/Circ.878 – MEPC/Circ.346	Completed	Goal (a)	Resulted in: – Human Element Vision, Principles and Goals for the Organization – Interim Guidelines for the application of Human Element Analyzing Process (HEAP)
	2.2 to develop a listing of IMO efforts under way which are addressing the human element	MSC 69/13 Annex 3 MSC 65/25 (item 15.20)	Ongoing	Goal (b)	Last report issued to MSC 69. The MSC at its 65th session assigned the MSC/MEPC Working Group on HE with responsibility for submitting to each session of the MSC and MEPC, as appropriate, a summary paper on IMO-related HE activities and progress thereon.
	2.3 to develop an index of regulatory references in IMO instruments which call for operational manuals, alarms, warnings and guidance signs	MSC 66/13/2	Completed	Goal (b)	Initial effort completed at MSC 66.
	2.4 to develop a draft listing of common terms used in human element analysis	MSC/Circ.813 – MEPC/Circ.330	Completed	Goal (c)	Initial effort completed at MEPC 39 and MSC 68. Circular includes provision for updates.
	2.5 to develop a list of studies and reports completed or underway relative to ship operation, management and HE initiatives	MSC 66/INF.2	Ongoing	Goal (e)	The United States through the United States Coast Guard is host to a database that can be accessed by the Administrations and the Non-Governmental Organizations.

	ACTIVITY	DOCUMENT	STATUS	SUPPORTED GOAL (From A.850(20))	COMMENTS
3	Human Element tutorials	-----	Completed	Goal (c) and (d)	Tutorials were hosted by the Organization during MEPC 37 and MSC 66.
4	Consider the mechanism and procedures by which FSA and the HE processes can be used in the future within the IMO rule-making process	MSC/Circ.878 – MEPC/Circ.346	Ongoing	Goal (a)	Resulted in Interim Guidelines for the application of Human Element Analysing Process (HEAP).
5	Incorporating HE into FSA	MSC 68/13/1	Ongoing	Goal (a)	Several proposals have been submitted.
6	Issue of Fatigue				
	6.1 Collect information on projects related to fatigue of seafarers		Ongoing	Goal (e)	The United States through the United States Coast Guard is host to a database that can be accessed by the Administrations and the Non-Governmental Organizations.
	6.2 Review the definition of the term "fatigue" used within the organization with the aim of obtaining a consistent, practical and meaningful definition	MSC/Circ.813 – MEPC/Circ.330	Completed	Goal (c)	Accepted definition as stated in MSC/MEPC Circular.
	6.3 Develop strategies in order to continue to develop a safety culture by addressing the issue of "fatigue"	A.772(18)	Ongoing	Goals (c) and (f)	Correspondence Group on Fatigue is currently working on practical guidance.

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ANNEX 6

PROPOSED WORK PLAN ON IMO-RELATED HUMAN ELEMENT ACTIVITIES.

	ACTIVITY	DOCUMENT	STATUS	SUPPORTED GOAL (From A.840(20))	COMMENTS
1.	Instruction to subcommittees containing the following: - Review the adequacy of requirements and recommendations for equipment and operating manuals and operational guidelines on board ships - Consider the simplification and standardization of terminology in operating manuals and symbols and signs used on board ships - Identify words and phrases used in IMO instruments relating to human performance criteria and determination of the extent to which they can be more specifically defined - Sub-Committees should considered the Human Element Analysing Process (HEAP) when developing amendments - Report to the Committees on their progress	MSC 64/24 Annex 29	Ongoing	Goals (a) and (b)	Sub-Committees should considered the Human Element aspect when developing amendments to existing regulations similar to work undertaken by the FP Sub-Committee while revising SOLAS chapter II-2 Manual on operational requirements for seafarers being developed.

	ACTIVITY	DOCUMENT	STATUS	SUPPORTED GOAL (From A.840(20))	COMMENTS
2.	To update on a continuous basis				
	2.1 The list of IMO efforts under way which are addressing the human element	MSC 69/13 Annex 3 MSC 64/24 (item 14.20)	Ongoing	Goal (b)	The MSC at its 64th session assign the MSC/MEPC Working Group on HE, responsibility for submitting to each session of the MSC and MEPC, as appropriate, a summary paper on IMO-related HE activities and progress thereon.
	2.2 The list of studies and reports completed or underway relative to ship operation, management and HE initiatives	MSC 66/INF.2	Ongoing	Goal (e)	The United States through the United States Coast Guard is host to a database that can be accessed by the Administrations and the Non-Governmental Organizations. Member Governments to supplement this database with more information on studies and investigation analyses from the Human Element point of view[5]

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[5] http://www,uscg.mil/humanelements

ANNEX 7

~~INTERIM~~ DRAFT REVISED GUIDELINES FOR THE APPLICATION OF FORMAL SAFETY ASSESSMENT (FSA) TO THE IMO RULE-MAKING PROCESS

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Note to the readers:

Underlined text means proposed additions to the FSA Interim Guidelines in MSC/Circ.829 & MEPC/Circ.335
~~Strikethrough~~ text means proposed deletion to the FSA Interim Guidelines in MSC/Circ.829 & MEPC/Circ.335

~~INTERIM~~ DRAFT REVISED GUIDELINES FOR THE APPLICATION OF FORMAL SAFETY ASSESSMENT (FSA) TO THE IMO RULE-MAKING PROCESS

1 INTRODUCTION

1.1 Purpose of FSA

1.1.1 Formal Safety Assessment (FSA) is a structured and systematic methodology, aimed at enhancing maritime safety, including protection of life, health, the marine environment and property, by using risk and cost/benefit assessments.

1.1.2 FSA can be used as a tool to help in the evaluation of new safety regulations or making a comparison between existing and possibly improved regulations, with a view to achieving a balance between the various technical and operational issues, including the human element, and between safety and costs.

1.1.3 FSA is consistent with the current IMO decision-making process and provides a basis for making decisions in accordance with resolutions A.500(XII) "Objectives of the Organization in the 1980's", and A.777(18) "Work Methods and Organization of Work in Committees and their Subsidiary Bodies".

1.1.4 The decision makers at IMO, through FSA, will be able to appreciate the effect of proposed regulatory changes in terms of benefits (e.g. expected reduction of lives lost or of pollution) and related costs incurred for the industry as a whole and for individual parties affected by the decision. FSA should facilitate development of regulatory changes equitable to the various parties thus aiding the achievement of consensus.

1.2 Scope of the Guidelines

1.2.1 These Guidelines are intended to outline the FSA methodology as a tool which may be applied in the IMO rule-making process. In order that FSA can be consistently applied by different parties, it is important that the process is clearly documented and formally recorded in a uniform and systematic manner. This will ensure that the FSA process is transparent and can be understood by all parties irrespective of their experience in the application of risk assessment and related techniques.

~~1.2.2 In the interim period, these Guidelines provide the basis for interested parties to perform trial applications aimed at demonstrating the potential of FSA within the IMO rule-making process.~~

1.3 Application

1.3.1 The FSA methodology can be applied by:

.1 an individual Administration or an organization having a consultative status with IMO when proposing amendments to safety and pollution prevention and response-related IMO instruments in order to analyse the implications of such proposals; or

.2 by the Committee, or an instructed subsidiary body, to review the overall framework of safety and environmental regulations, for instance for a particular ship type or hazard, aiming at identifying priorities or areas of concern of the current regulations.

1.3.2 It is not intended that FSA should be applied in all circumstances, but its application would be particularly relevant to proposals which may have far-reaching implications in terms of either costs (to society or the maritime industry), or the legislative and administrative burdens which may result. FSA may also be useful in those situations where there is a need for risk reduction but the required decisions regarding what to do are unclear, regardless of the scope of the project. In these circumstances, FSA will enable the benefits of proposed changes to be properly established, so as to give Member Governments a clearer perception of the scope of the proposals and an improved basis on which to take decisions.

1.3.3 Guidance for practical application of FSA to the IMO rule-making process are given in appendix 1.

2 BASIC TERMINOLOGY

2.1 The following definitions apply in the context of these guidelines:

Accident	:	An unintended event involving fatality, injury, ship loss or damage, other property loss or damage, or environmental damage
Accident category	:	A designation of accidents reported in statistical tables according to their nature, e.g. fire, collision, grounding, etc.
Consequence	:	The outcome of an accident
Frequency	:	The number of occurrences per unit time (e.g. per year)
Hazard	:	A potential to threaten human life, health, property or the environment
Initiating event	:	The first of a sequence of events leading to a hazardous situation or accident
Risk	:	The combination of the frequency and the severity of the consequence
Risk control measure	:	A means of controlling a single element of risk

3 METHODOLOGY

3.1 Process

3.1.1 FSA should comprise the following steps:

.1 identification of hazards;

.2 risk assessment;

.3 risk control options;

.4 cost benefit assessment; and

.5 recommendations for decision-making.

3.1.2 Figure 1 is a flow chart of the FSA methodology. The process begins with the decision-makers defining the problem to be assessed along with any relevant boundary conditions or constraints. These are presented to the group who will carry out the FSA and provide results to the decision-makers for use in their resolutions. In cases where decision makers require additional work to be conducted, they would revise the problem statement or boundary conditions or constraints, and resubmit this to the group and repeat the process as necessary. Within the FSA methodology, step 5 interacts with each of the other steps in arriving at decision-making recommendations. The group carrying out the FSA process should comprise suitably qualified and experienced people to reflect the range of influences and the nature of the "event" being addressed.

3.1.3 The depth or extent of application of the methodology should be commensurate with the nature and significance of the problem. However, before starting the detailed application, a coarse application is suggested for the relevant ship type or hazard category, in order to include all aspects of the problem under consideration. Whenever there are uncertainties, e.g. in respect of data or expert judgement, the significance of these uncertainties should be assessed.

3.1.4 Characterization of hazards and risks should be both qualitative and quantitative, that is both descriptive and mathematical, consistent with the available data, and it should be broad enough to include a comprehensive range of options to reduce risks.

3.1.5 A hierarchical screening approach should be utilized. This would ensure that excessive analysis is not performed by utilising relatively simple tools to perform initial analyses, the results of which can be used to either support decision-making (if the degree of support is adequate) or to scope/frame more detailed analyses (if not). The initial analyses would therefore be primarily qualitative in nature, with increasing degrees of detail and quantification coming in subsequent analyses as necessary. Examples of basic risk assessment tools for the coarse qualitative analyses include What If and Checklist Analyses. More detailed analytic tools such as Failure Modes and Effects Analysis, and Hazard and Operability (HazOp) analysis would be illustrative of the detailed qualitative and coarse quantitative tools. Finally, probabilistic reliability analysis fault tree analysis, and human reliability analysis form examples of detailed quantitative tools (although the latter two can be used in a less detailed and less quantitative form if desired).

3.2 Problem definition

3.2.1 The problem under analysis and its boundaries should be carefully defined, in relation to the regulations under review or to be developed. The definition of the problem should be consistent with operational experience and current requirements, by taking into account all relevant aspects. Those which may be considered relevant when addressing ships (not necessarily in order of importance) are:

.1 ship category (e.g. type, length or gross tonnage range, new or existing, type of cargo);

.2 ship systems or functions (e.g. layout, subdivision, type of propulsion);

.3 ship operation (e.g. operations in port and/or during navigation);

.4 external influences on the ship (e.g. Vessel Traffic System, weather forecasts, reporting, routeing);

.5 accident category (e.g. collision, explosion, fire); and

.6 risks associated with consequences such as injuries and/or fatalities to passengers and crew, environmental impact, damage to the ship or port facilities, or commercial impact.

3.3 Generic model

3.3.1 In general, the problem under consideration should be characterized by a number of functions. Where the problem relates for instance to a type of ship, these functions include carriage of payload, communication, emergency response, manoeuvrability, etc. Alternatively, where the problem relates to a type of hazard, for instance fire, the functions include prevention, detection, alarm, containment, escape, suppression, etc.

3.3.2 For application of FSA, a generic model should therefore be defined to describe the functions, features, characteristics and attributes which are common to all ships of the type, or relevant to the problem under concern.

3.3.3 The generic model should not be viewed as an individual ship in isolation, but rather as a collection of systems, including organizational, management, operational, human, electronic, and hardware, which fulfill the defined functions. The functions and systems should be broken down to an appropriate level of detail. Aspects such as the interaction of functions and systems, and the extent of their variability, should be addressed.

3.3.4 A comprehensive view, such as the one shown in figure 2, should be taken, recognizing that the ship "hardware" (i.e. the technical and engineering system), which is governed by physical laws, is in the centre of an integrated system. The "hardware" is integrally related to the "software" (i.e. the passengers and crew), which is a function of human behaviour. The "software" interacts with the organizational and management infrastructure and those personnel involved in ship and fleet operations, maintenance and management. These systems are related to the outer environmental context, which is governed by pressures and influences of all parties interested in shipping and the public. Each of these systems is dynamically affected by the others.

3.4 Information and data

3.4.1 The availability of suitable data necessary for each step of the FSA process is very important. When data are not available, expert judgement, physical models, simulations and analytical models may be used to achieve valuable results. Consideration should be given to those data which are already available at IMO (e.g. casualty and deficiency statistics), and to potential improvements in those data in anticipation of an FSA implementation (e.g. a better specification for recording relevant data including the primary causes, underlying factors and latent factors associated with a casualty).

3.4.2 Data concerning incident reports, near misses and operational failures may be very important for the purposes of making more balanced, proactive and cost-effective legislation. A judgement on the value of data which can be collected should be carried out in order to identify uncertainties and limitations, and to assess the degree of reliance which should be placed on the available data.

3.5 Incorporation of the human element

3.5.1 The human element is one of the most important contributory aspects to the causation and avoidance of accidents. Human element issues throughout the integrated system shown in figure 2 should be systematically treated within the FSA framework, associating them directly with the occurrence of accidents, underlying causes or influences. Appropriate techniques for incorporating human factors should be used.

<u>3.5.2 As shown in figure 3, there are two scenarios for entering the proposed process. The first scenario would be to enter with a proposed action for IMO (new, revised or deleted circular, guidance or other policy change). This would first be screened for basic human element considerations and then, if needed and appropriate, go through a Formal Safety Assessment, as shown in the process above. Should changes be made as a result of the FSA, it would then be re-screened for human element considerations as above. The second scenario would be to enter with an issue for which no action is proposed. This would then be referred to the FSA process first (using the revised FSA applicability criteria outlined above) and subsequently (once recommendations for IMO action are developed) run through the human element screening.</u>

<u>3.5.3 The human element can be incorporated into the FSA process by using various techniques, such as human reliability analysis (HRA). Guidance to the use of HRA within FSA is given at appendix 2.</u>

4 FSA STEP 1 - IDENTIFICATION OF HAZARDS

4.1 Scope

4.1.1 The purpose of step 1 is to identify and generate a prioritized list of hazards, specific to the problem under review. This purpose is achieved by the use of standard techniques to identify hazards which can contribute to accidents, and by screening these hazards using a combination of available data and judgement. The hazard identification exercise should be undertaken in the context of the functions and systems generic to the ship type or problem being considered, which were established in paragraph 3.3, by reviewing the generic model.

4.2 Methods for hazard identification

4.2.1 The approach used for hazard identification generally comprises a combination of both creative and analytical techniques, the aim being to identify as many relevant hazards as possible. The creative element is to ensure that the process is proactive, and not confined only to hazards that have materialized in the past. It typically consists of structured group reviews aiming at identifying the causes and effects of accidents and relevant hazards. Consideration of functional failure may assist in this process. The group carrying out such structured reviews should include experts in the various appropriate aspects, such as ship design and operations and specialists to assist in the hazard identification process and incorporation of the human element. A structured group review session may last over a number of days. The analytical element ensures that previous experience is properly taken into account, and typically makes use of background information (for example applicable regulations and codes, available statistical data on accident categories and lists of hazards to personnel, hazardous substances, ignition sources, etc.). Examples of hazards relevant to shipboard operations are shown in appendix ~~1~~ 3.

4.2.2 A coarse analysis of possible causes and outcomes of each accident category should be made by using standard techniques (such as fault and event trees, HAZOPs, FMEAs, etc. as described in appendix ~~2~~4), to be chosen according to the problem under concern.

4.~~4~~3 Ranking of identified hazards

4.3.1 The identified hazards relevant to the problem being considered, and established at an earlier stage of step 1, should be screened to prioritize them and to discard scenarios judged to be of minor significance. Screening is undertaken using available data, supported by judgement, on the frequency of different outcomes of accident ~~categories~~ scenarios. A risk matrix, as shown in figure ~~3~~4, may be used. Guidance to the use of the risk matrix for the initial ranking of accident scenarios is given at appendix 5.

4.~~5~~4 Results

4.4.1 The output from step 1 comprises:

.1 a prioritized list of hazards; and

.2 preliminary description of the development of hazards to final outcomes.

5 FSA STEP 2 - RISK ASSESSMENT

5.1 Scope

5.1.1 The purpose of step 2 is to identify the distribution of risk, thus allowing attention to be focused upon high risk areas, and to identify and evaluate the factors which influence the level of risk. ~~Step 2 aims to establish the relationship between the regulatory regime at the IMO and the occurrence and consequence of accidents~~. This should enable appropriate regulatory changes to be introduced to reduce risks.

5.1.2 Different types of risk (i.e. risks to people, the environment or property) should be addressed as appropriate to the problem under consideration, together with the units in which they are expressed, as described in appendix ~~3~~ 6.

5.1.3 This purpose can be achieved by first constructing and quantifying a diagram (in this context called a risk contribution tree) to display the distribution of risk, as indicated in figure ~~4~~5. This may be determined principally from accident data, failure data or other sources of information (as described in paragraph 5.2 below).

5.1.4 Further diagrams (in this context called regulatory impact diagrams) may be constructed to represent the network of influences linking the regulatory regime to the occurrence of events, as ~~indicated in figure 5~~ described in appendix 7. ~~These factors should be quantified using~~ These diagrams may be used when expert judgement is needed to highlight in a qualitative (not absolute) way these influences. ~~and hence facilitate effective regulation~~

5.2 Risk contribution tree

5.2.1 The risk contribution tree may be used as a mechanism for displaying diagrammatically the distribution of risk amongst different accident categories and sub-categories, as shown in figure ~~4~~5. Structuring the tree starts with the accident categories, which may be divided into sub-categories to the extent that available data allow and logic dictates, in order to describe the prioritized list of hazards. The preliminary fault and event trees from step 1 can be developed to demonstrate how direct causes initiate and combine to cause accidents (using fault trees), and also how accidents may progress further to result in different magnitudes of loss (using event trees). Whilst the example makes use of fault and event tree techniques, other established methods could be used if appropriate.

5.2.2 Quantifying the contribution to risks is typically undertaken in three stages using available accident statistics:

.1 the categories and sub-categories of accident are quantified in terms of the frequency of accidents;

.2 the magnitude of accident outcomes is quantified in risk terms; and

.3 the distribution of outcome magnitudes across all the sub-categories of accident is determined in risk terms, so as to display which categories contribute how much risk.

~~5.3 Regulatory impact diagram~~

~~5.3.1 In general, the structure of a regulatory impact diagram, such as the one shown in figure 5 1 of appendix 7, may be used in an FSA application to reflects influences at various levels, including direct causes, their underlying factors and regulatory policy. The regulatory impact diagram can represent, respectively, the influences affecting the "likelihood" of an accident occurring, the "escalation" of an accident and "mitigation" aspects , such as the evacuation of people from a stricken ship, containment of oil pollution, clean-up, etc. (the latter would include consideration of emergency preparedness) . These influences link failures at an operational level with their direct causes and with the underlining organizational and regulatory influences.~~

~~5.3.2 Regulatory impact diagrams can be used in a comparative (i.e. not absolute) way. Where there is uncertainty in the risk contribution tree (e.g. inadequate data to determine with confidence the frequency of a particular sub-category of accident) sensitivity studies may be carried out.~~

~~5.3.3 Guidance to the use of regulatory impact diagrams (RID) within an FSA application is given at appendix 7.~~

5.43 Results

5.3.1 The output from step 2 comprises:

.1 an identification of the high risk areas needing to be addressed;

.2 an identification of the principal influences within the overall regulatory regime that affect the level of risk; and

.3 a re-evaluation of risk for each risk control option identified in step 3.

6 FSA STEP 3 - RISK CONTROL OPTIONS

6.1 Scope

6.1.1 The purpose of step 3 is to propose effective and practical risk control options, comprising the following three principal stages:

.1 focusing on areas of risk needing control;

.2 identifying potential risk control measures; and

.3 grouping risk control measures into practical regulatory options.

6.1.2 Step 3 aims to create risk control options that address both existing risks and risks introduced by new technology or new methods of operation. Both historical risks and newly identified risks (from steps 1 and 2) should be considered, producing a wide range of risk control measures. Techniques designed to address both specific risks and underlying causes should be used.

6.2 Areas Needing Control

6.2.1 The purpose of focusing is to screen the output of step 2 so that effort is focused on the areas most needing risk control. The main aspects to making this assessment are to review:

.1 risk levels, by considering frequency of occurrence together with the severity of outcomes. Accidents with an unacceptable risk level become the primary focus;

.2 probability, identifying the areas of the risk contribution tree that have the highest probability of occurrence. These should be addressed irrespective of the severity of the outcome;

.3 severity, identifying the areas of the risk contribution tree that contribute to high severity outcomes. These should be addressed irrespective of their probability; and

.4 confidence, identifying areas where the risk contribution tree has considerable uncertainty either in risk, severity or probability.

6.3 Potential Risk Control Measures

6.3.1 Structured review techniques are typically used to identify new risk control measures for risks that are not sufficiently controlled by existing measures. These techniques may encourage the development of appropriate measures and include risk attributes and causal chains. Risk attributes relate to how a measure might control a risk, and causal chains relate to where, in the "initiating event to fatality" sequence, risk control can be introduced.

6.3.2 Risk control measures (and subsequently risk control options) have a range of attributes. These attributes may be categorized according to the examples given in appendix ~~4~~ 8.

6.3.3 The prime purpose of assigning attributes is to facilitate a structured thought process to understand how a risk control measure works, how it is applied and how it would operate. Attributes can also be considered to provide guidance on the different types of risk control that could be applied. Many risks will be the result of complex chains of events and a diversity of causes. For such risks the identification of risk control measures can be assisted by developing causal chains which might be expressed as follows:

causal factors ® *failure* ® *circumstance* ® *accident* ® *consequences*

6.3.4 Risk control measures should in general be aimed at one or more of the following:

.1 reducing the frequency of failures through better design, procedures, organizational polices, training, etc;

.2 mitigating the effect of failures, in order to prevent accidents;

.3 alleviating the circumstances in which failures may occur; and

.4 mitigating the consequences of accidents.

6.4 Risk control options

6.4.1 The purpose of this stage is to group risk control measures into a limited number of well thought out practical regulatory options. There is a range of possible approaches to grouping individual measures into options. The following two approaches, related to likelihood and escalation, can be considered:

.1 "general approach" which provides risk control by controlling the likelihood of initiation of accidents, and may be effective in preventing several different accident sequences; and

.2 "distributed approach" which provides control of escalation of accidents, together with the possibility of influencing the later stages of escalation of other, perhaps unrelated, accidents.

6.4.2 In generating the risk control options, the interested entities, who may be affected by the combinations of measures proposed, should be identified.

6.5 Results

6.5.1 The output from step 3 comprises:

.1 a range of risk control options, which are assessed for their effectiveness in reducing risk by re-evaluating step 2; and

.2 a list of entities affected by the identified risk control options.

7 FSA STEP 4 - COST BENEFIT ASSESSMENT

7.1 Scope

7.1.1 The purpose of step 4 is to identify benefits and costs associated with the implementation of each risk control option identified and defined in step 3. A cost benefit assessment may consist of the following stages:

.1 consider the risks assessed in step 2, both in terms of frequency and consequence, in order to define the base case in terms of risk levels of the situation under consideration;

.2 arrange the risk control options, defined in step 3, in a way to facilitate understanding of the costs and benefits resulting from the adoption of an option;

.3 estimate the pertinent costs and benefits for all risk control options;

.4 estimate and compare the cost effectiveness of each option, in terms of the cost per unit risk reduction by dividing the net cost by the risk reduction achieved as a result of implementing the option; and

.5 rank the risk control options from a cost-benefit perspective in order to facilitate the decision making recommendations in step 5 (e.g. to screen those which are not cost effective or impractical).

7.1.2 Costs should be expressed in terms of life cycle costs, and may include initial, operating, training, inspection, certification, etc. Benefits may include reductions in the costs associated with fatalities, injuries, casualties, environmental damage and clean-up, indemnity of third party liabilities, etc., and an increase in the average life of ships.

7.2 Application

7.2.1 The evaluation of the above costs and benefits could be carried out by using various methods and techniques. Such a process should be conducted for the overall situation and then for those interested entities which are the most influenced by the problem under concern.

7.2.2 In general, an interested entity can be defined as the person, organization, company, coastal State, flag State, etc., who is directly or indirectly affected by an accident, or by the cost effectiveness of the proposed new regulation. In the initial stages of FSA implementation, different interested entities with similar interests can be grouped together for the purposes of applying the FSA methodology and identifying decision making recommendations.

7.2.3 The results of a cost benefit assessment may be presented as a loss matrix. An example format of a loss matrix is given in figure ~~5~~6. The loss matrix may be used for risk control options based on cost benefit analysis.

7.3 Results

7.3.1 The output from step 4 comprises:

.1 costs and benefits for each risk control option identified in step 3 from an overview perspective;

.2 costs and benefits for those interested entities which are the most influenced by the problem under concern; and

.3 cost effectiveness expressed in terms of net cost per unit risk reduction.

8 FSA STEP 5 -RECOMMENDATIONS FOR DECISION MAKING

8.1 Scope

8.1.1 The purpose of step 5 is to define the recommendations which should be presented to the relevant decision makers. The recommendations would be based upon the comparison and ranking of hazards and their underlying causes; the comparison and ranking of risk control options as a function of associated costs and benefits; and the identification of those risk control options which keep risks as low as reasonably practicable.

8.1.2 The basis on which these comparisons should be made should take into account that, in ideal terms, all those entities that are significantly influenced in the area under concern should be equitably affected by the introduction of the proposed new regulation. However, taking into consideration the difficulties of this type of assessment, the approach should be, at least in the earliest stages, as simple and practical as possible.

8.2 Results

8.2.1 Output from this step can provide an objective comparison of alternative options, based on potential reduction of risks and cost effectiveness, in areas where legislation or rules should be reviewed or developed. Recommendations should be usable by decision makers at all levels and in a variety of contexts within the IMO, without a requirement for specialist expertise. This step should also provide feedback information to review the results generated in the previous steps.

9 PRESENTATION OF FSA RESULTS

9.1 To facilitate the common understanding and use of FSA at IMO in the rule-making process, each report of an FSA process, the standard format for which is shown at ~~annex 2~~ appendix 9, should:

.1 provide a clear statement of the final recommendations:

.2 list the principal hazards, risks, costs and benefits identified during the assessment;

.3 explain the basis for significant assumptions, limitations, data models and inferences used or relied upon in the assessment or recommendations;

.4 describe the sources, extent and magnitude of significant uncertainties associated with the assessment or recommendations; and

.5 describe the composition and expertise of the group that performed the FSA process.

9.2 Those submitting the results of an FSA process should provide timely and open access to relevant supporting documents, and a reasonable opportunity for, and a mechanism to incorporate, comment.

FIGURE 1
FLOW CHART OF THE FSA METHODOLOGY

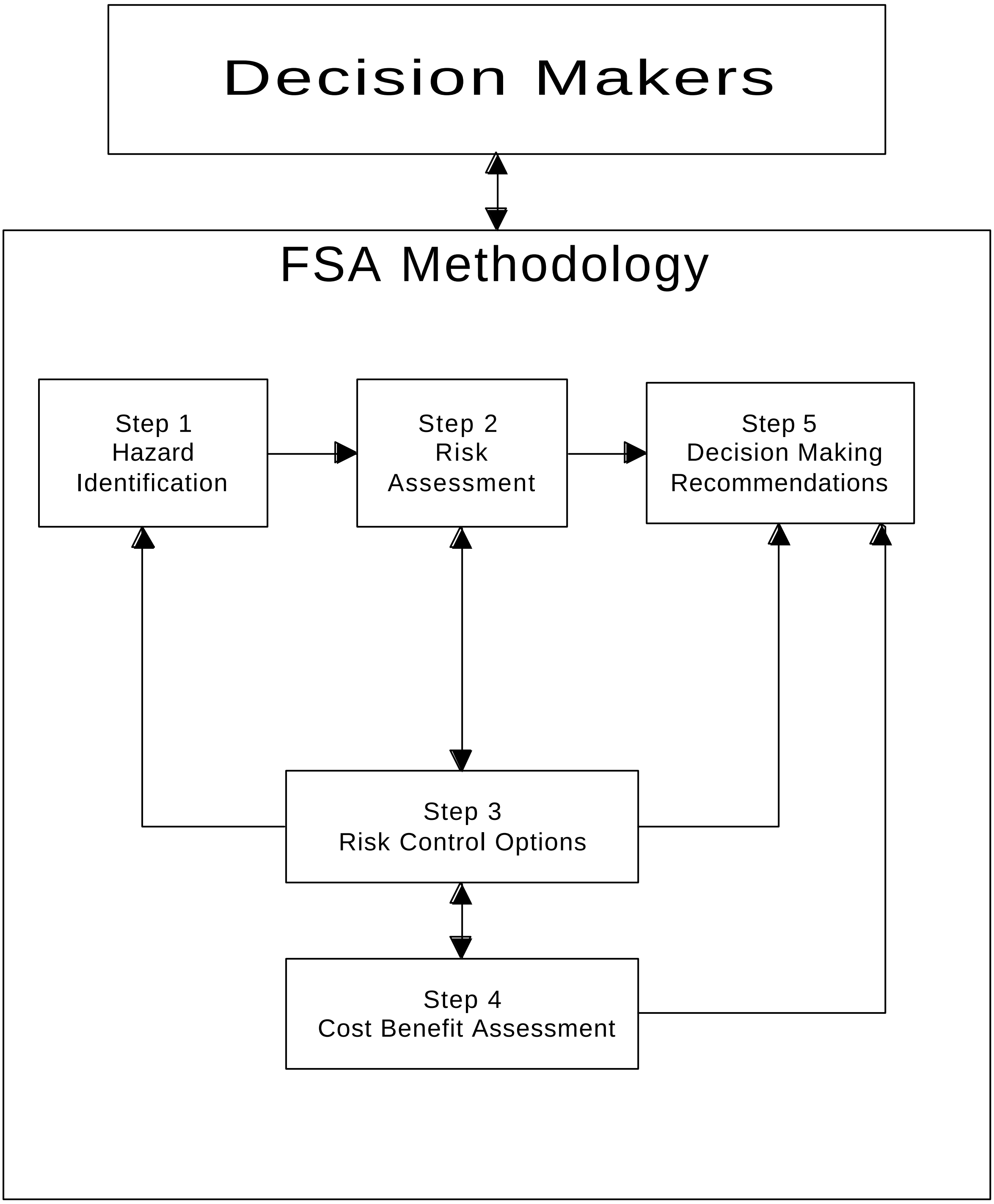


FIGURE 2

Components of the Integrated System

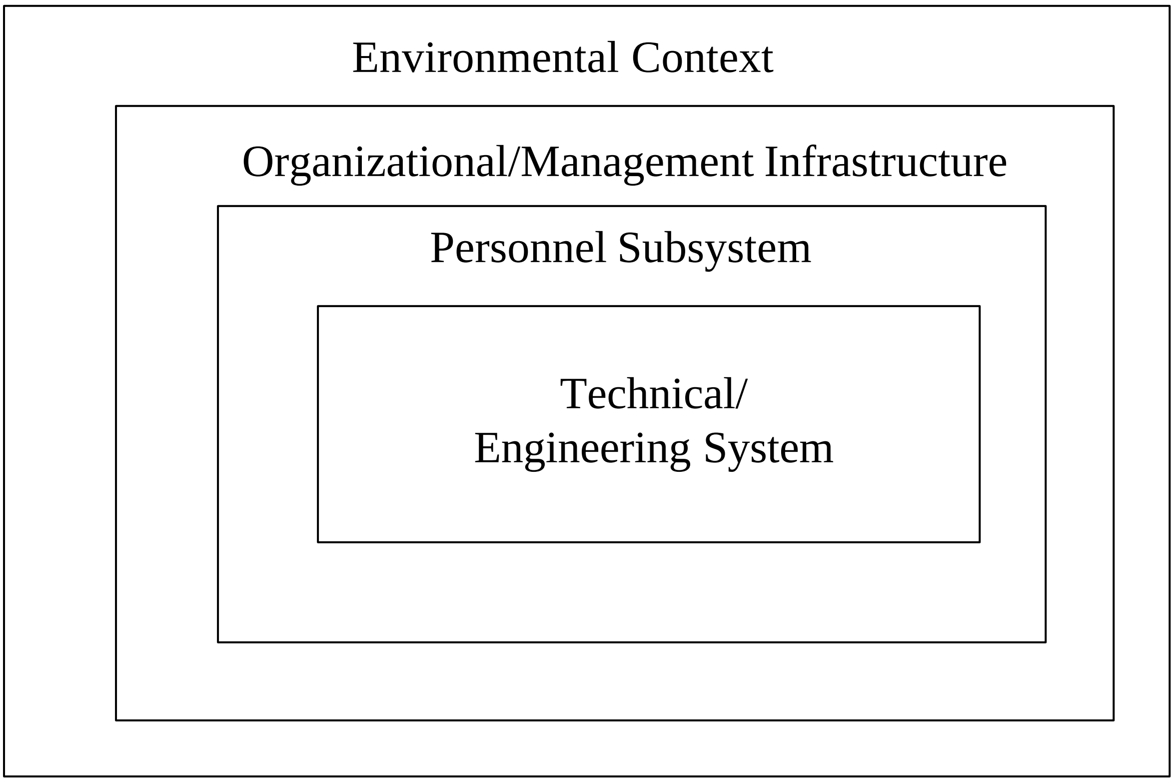


FIGURE 3
INCORPORATION OF HE AND FSA INTO THE DECISION MAKING PROCESS

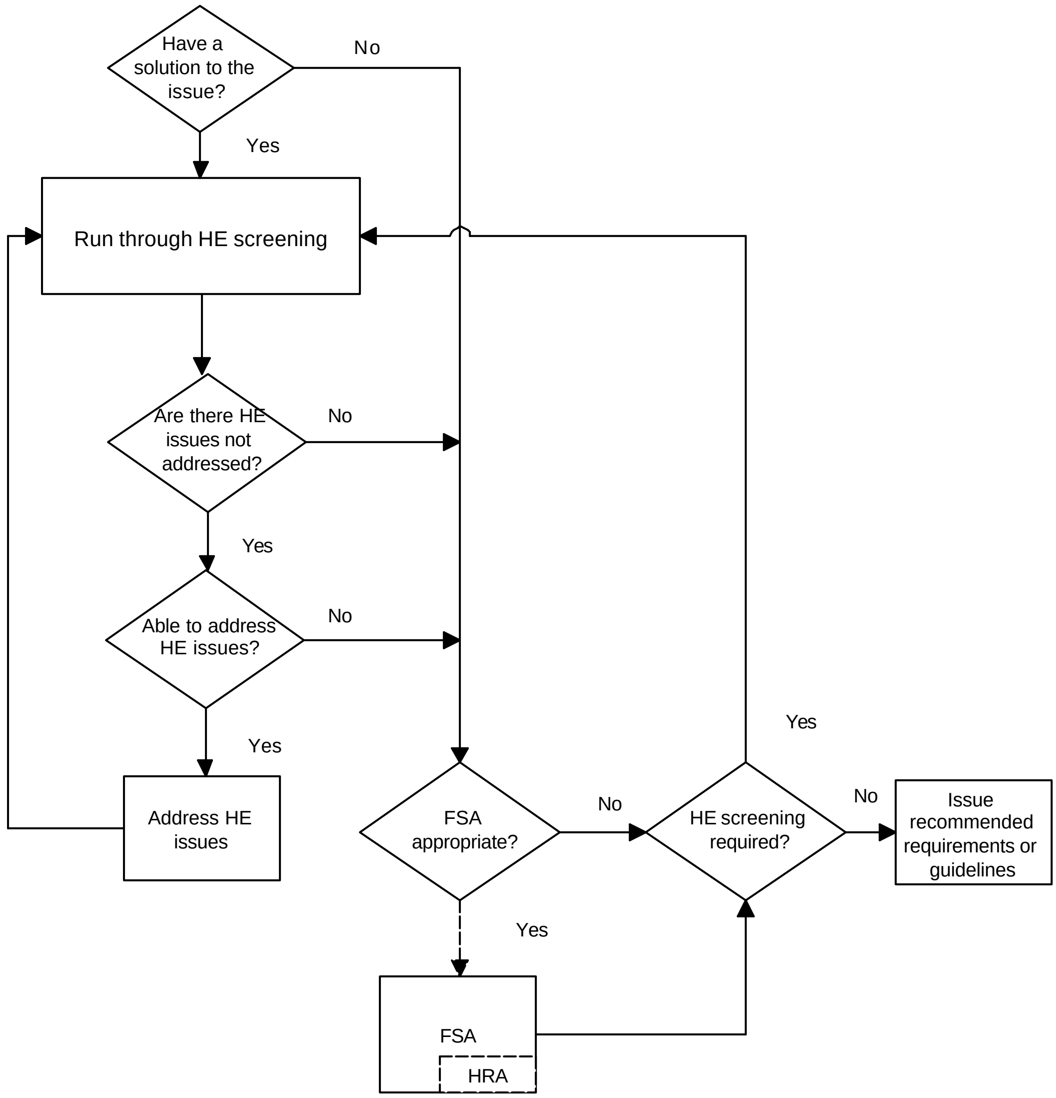
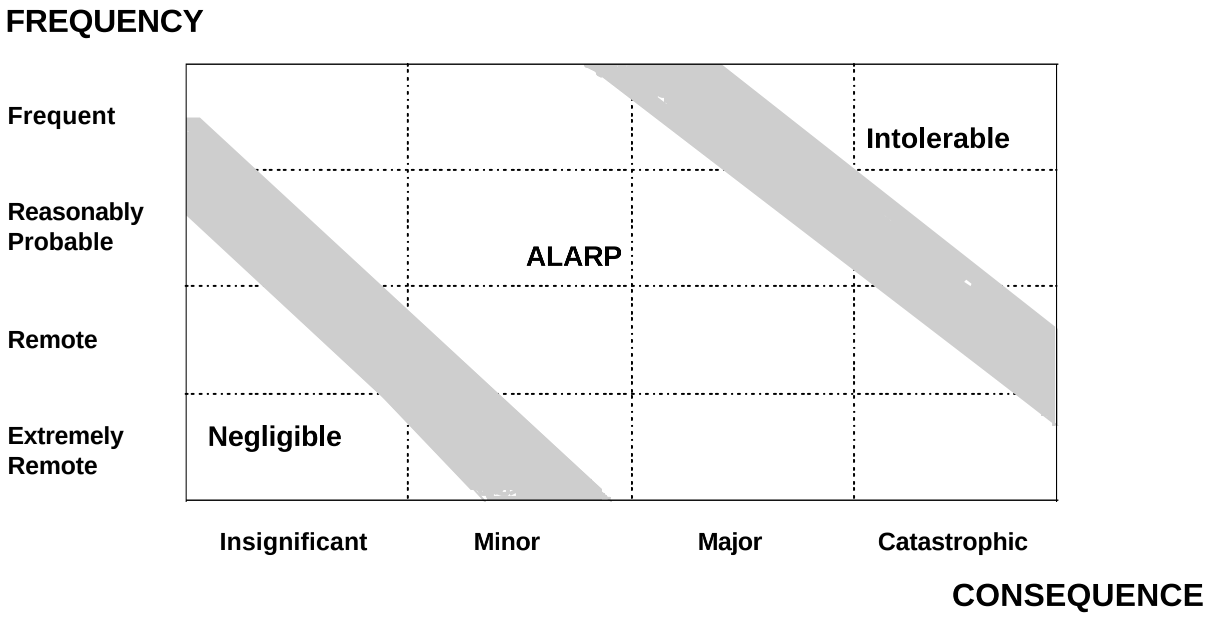


FIGURE 4

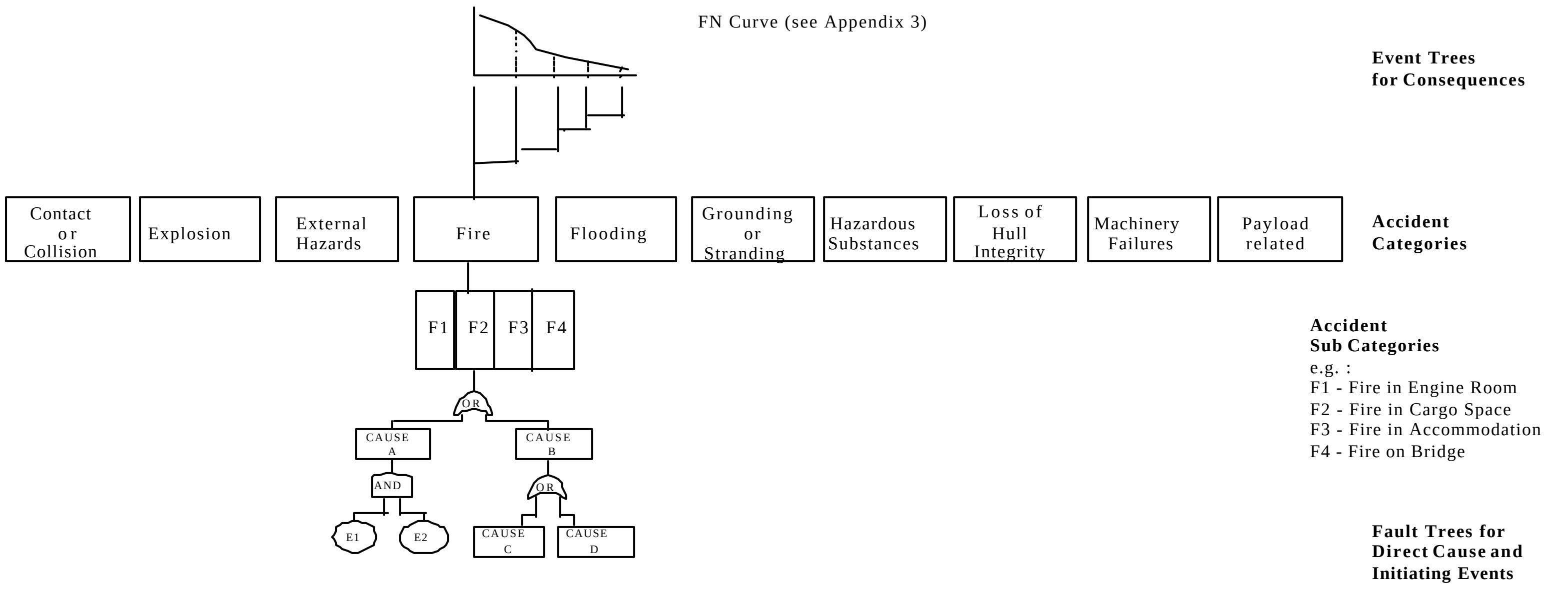
RISK MATRIX



ALARP = As Low As Reasonably Practicable
Note: Risk level boundaries (Negligible/ALARP/Intolerable) are purely illustrative

FIGURE 5

EXAMPLE OF A RISK CONTRIBUTION TREE*



*As defined in the context of these Guidelines.

FIGURE ~~5~~6

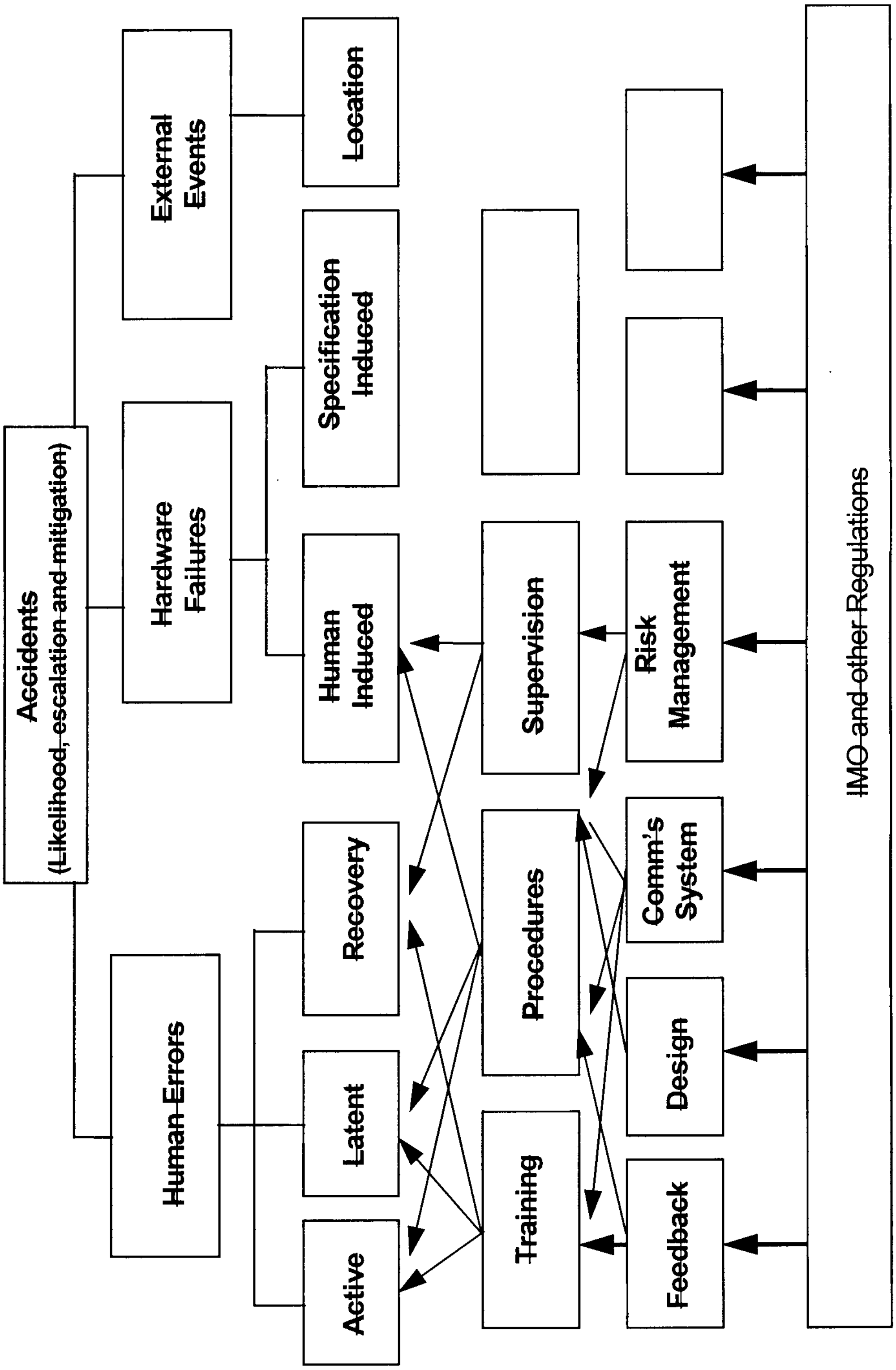
EXAMPLE OF LOSS MATRIX

Table B.1 Ship Accident Loss (£ per ship year)

Accident Type	Ship Accident Cost	Environmental Damage and Clean Up	Risk to Life	Risk of injuries and ill Health	Total Cost
	£	£/tonne x number of tonnes	Fatalities x £2m	QALY x £25 000	£
Collision					
Contact					
Foundered					
Fire/explosion					
Hull damage					
Machinery damage					
War loss					
Grounding					
Other ship accidents					
Other oil spills					
Personal accidents					
TOTAL					

~~FIGURE 5~~

~~EXAMPLE OF A REGULATORY IMPACT DIAGRAM~~ *



* ~~As defined in the context of these guidelines~~

APPENDIX 1

TAKEN FROM MSC 71/WP.15 ADD.1, ANNEX 5 AND ANNEX 7

~~DRAFT GUIDELINES~~ GUIDANCE FOR PRACTICAL APPLICATION OF FORMAL SAFETY ASSESSMENT (FSA) TO THE IMO RULE-MAKING PROCESS

Introduction

~~1 The Interim Guidelines for the Application of Formal Safety Assessment to the IMO Rule-Making Process (MSC/Circ.829/MEPC/Circ.335) set out the methodology for undertaking and reporting FSA studies in the IMO rule making process.~~

1 The Interim Guidelines identify two areas of application:

.1 by a Member State or an organisation having a consultative status with the IMO (hereinafter called Member), when proposing amendments to safety and pollution prevention instruments, to support or analyse the implications of such proposals; or

.2 by a Committee or instructed subsidiary body, to provide a balanced view of a framework of regulations, so as to identify priorities and areas of concern, and to analyse the benefits and implications of proposed changes.

~~3 The execution of an FSA study requires the participation of persons with suitable qualifications and experience, i.e. persons with appropriate competencies. Depending on the scope of the particular study, these competencies may include a wide range of disciplines, together with skills in risk and cost benefit assessment, and the human element~~.

2 ~~However~~ Recommendations resulting from an FSA study should aim to be used by decision makers at all levels and in a variety of contexts at the IMO, without a requirement of specialist expertise. For this purpose, an FSA study should be open and transparent for review by all interested Member States and non-governmental organisations which have not participated in the conduct of the FSA study.

Application of FSA by a Member

~~4~~3 A Member Government or an organization having a consultative status with IMO, or a pool of Members, may decide to carry out an FSA study and submit its results for consideration by a Committee or instructed subsidiary body. The scope of the FSA study, definition of the problem and its boundaries ~~will~~ should be decided by the Member(s) conducting the study, in the context of the submitted proposal. The costs involved in carrying out the study ~~will~~ should be covered by the Member(s) conducting the study, who will also co-ordinate and keep responsibility for the work of subcontractors, if any.

~~5~~4 The Member(s) carrying out the FSA study will make its/their best efforts to ensure that the report is presented in accordance with the Standard Format for Reporting FSA Trial Applications, given in annex 2 of the FSA Interim Guidelines. It is important that the FSA report includes the names and credentials of the experts who have carried out or have been involved in the FSA study.

Review of a FSA study carried out by a Member

~~6~~5 The Committee or an instructed subsidiary body ~~will~~ should consider the submission of an FSA study and decide, on a case by case basis, the most appropriate course of action. When the subject is sufficiently clear, the Committee can form an opinion about the FSA study and its relevant proposals, and decide accordingly. In other circumstances, the Committee may decide that a review is necessary to validate the FSA study and its findings.

~~7~~6 The review process should be carried out within the Organisation, e.g. by an intersessional correspondence group and/or working group established by the Committee for that purpose.

~~8~~7 The terms of reference of such a review should be established by the Committee or an instructed subsidiary body, based on the matter under consideration. For instance, the terms of reference may include:

.1 evaluation of the methodology applied and verification that it is in accordance with the FSA Interim Guidelines;

.2 evaluation of the appropriateness of the scenarios applied, assumptions made and limitations of the FSA study with regard to the significance of the findings;

.3 evaluation of whether the risks and risk control options have been evaluated in an appropriate manner; and

.4 presentation of the results of the review, in clear and comprehensive terms, including any recommendations for the IMO rule-making process.

~~9~~8 Participation in the review will be voluntary and open to all Member States and non-governmental organizations. All fields of expertise necessary for carrying out the review should be properly covered and the review should be as wide as possible.

~~10~~9 The Members having carried out the FSA study should provide timely and open access to relevant supporting documents, and any reasonable opportunity to take into consideration the comments received.

~~11~~10 The results of the review should be presented to the Committee or instructed subsidiary body, as appropriate.

Application of FSA by a Committee or an instructed sub-committee

~~12~~11 The Committee may decide to carry out an FSA study following:

.1 a proposal by a Member;

.2 a proposal from a subsidiary body; or

.3 discussion in the Committee of an agenda item.

~~13~~12 There are different options which may be followed by the Committee for undertaking the FSA study. In some circumstances, for instance when a proposal has far reaching implications and requires a balanced view between all relevant issues, the Committee may decide that the FSA study should be carried out by an instructed Sub-Committee, as described in paragraphs 15 to 24 below.

~~14~~13 Further options for undertaking an FSA study may also be appropriate, one of which could be to invite a Member, or a pool of Members, to carry out the FSA study and report its results for consideration by the Committee. The Member(s) accepting this proposal could proceed according to the steps given in paragraphs 4 to 11 above.

~~15~~14 In cases where the Committee decides that the study should be carried out by instructed sub-committee(s) the FSA study may be conducted in accordance with the flow chart shown in figure 1, as described below.

~~16~~15 The Committee may decide to establish a working group, instructed to:

.1 develop the terms of reference for undertaking the FSA study;

.2 propose a list of required competencies;

.3 develop and execute a project management plan;

.4 co-ordinate the conduct of the FSA study;

.5 validate the FSA study, when necessary; and

.6 report the results of the FSA study to the Committee, for information and approval.

~~17~~16 The terms of reference of an FSA study may include, *inter alia*:

.1 the definition of the problem under consideration and its boundaries (paragraph 3.2 of the Interim Guidelines);

.2 characterization of the problem under consideration, for example in terms or features, characteristics and attributes which are relevant to the problem concerned (paragraph 3.3 of the Interim Guidelines);

.3 the organization and tasks proposed for carrying out the 5 steps of the FSA process, including instructions to the relevant subsidiary bodies; and

.4 the list of competencies required for carrying out each step of the FSA study.

~~18~~17 The Committee should examine the draft terms of reference developed by the working group, including in particular the necessary competencies, for approval. On the basis of the approved terms of reference, the Committee will:

.1 instruct the sub-committee(s) to undertake the FSA study (for instance a sub-committee or several sub-committees);

.2 endorse the list of competencies for carrying out each step of the FSA study; and

.3 invite Members willing to participate in the conduct of the FSA study to provide persons with the required competencies.

~~19~~18 Members interested in participating in the FSA study should provide the Committee with a list of persons proposed to participate in the sub-committees instructed to carry out the FSA study, together with details of their relevant competencies. The working group should determine that such a list, when completed, covers the competencies deemed necessary for carrying out each step of the FSA study, and report to the Committee to decide as appropriate.

~~20~~19 Each instructed subsidiary body should carry out the parts of the FSA study assigned to them. Any progress reports that the Committee may require, and, on completion of the FSA study, the final report should be submitted to the Committee. This final report should be in accordance with the Standard Reporting Format, given in annex 2 of the FSA Interim Guidelines.

~~21~~20 Interim reports may be submitted to the working group for the purposes of providing inputs to other parts of the process and enabling the working group to facilitate and monitor progress according to the project plan. The working group should review these reports and inform the Committee whether the FSA study proceeds in accordance with the approved project management plan. The working group should also propose necessary corrective actions, if any.

~~22~~21 In addition to the final report submitted to the Committee by the sub-committees undertaking the FSA study, the working group should, at the completion of the FSA study, present to the Committee a summary report, which may include, *inter alia*:

.1 an evaluation that the methodology applied is in accordance with the Interim Guidelines;

.2 any proposals for improvement of the Interim Guidelines;

.3 deviations, if any, from the terms of reference approved by the Committee, and reasons therefore; and

.4 a list of recommendations resulting from the FSA study for a decision by the Committee.

~~23~~22 The Committee should receive the recommendations made by the working group and decide as appropriate.

~~24 At the end of the FSA study, the working group will be disbanded.~~

Review of a FSA study carried out by the Committee or an instructed sub-committee

~~25~~23 Based on the discussion of the FSA final and summary reports, the Committee may decide to carry out a review of the FSA study, similar to the guidelines given in paragraphs 6 to 11 above.

Participation of experts in an FSA Study

24 The participation of experts in the various fields is an essential part for the success of an FSA application. The team carrying out the FSA study should be selected in accordance with the area of interest of the study and related problems. A number of other experts should be involved to gather expert views and judgements throughout the 5 steps of the FSA process.

25 The team carrying out an FSA study should cover the fields of expertise necessary to progress within the 5 steps of the FSA process. The composition of the team depends on the type of problem and level of detail of the assessment. For instance, the team might include:

.1 experts in risk assessment techniques;

.2 experts in statistical data gathering and analysing;

.3 experts involved in casualty investigations;

.4 experts in the human element;

.5 experts in the applicable rules and regulations;

.6 experts from the technical, operational and organizational field, (e.g.: designers, builders and operators);

.7 experts in consequence assessment (e.g.: SAR, salvage and environment protection); and

.8 experts in cost benefit assessment (e.g.: financiers and insurers).

~~3~~ 26 The team carrying out an FSA study ~~is likely to~~ may involve ~~a number of~~ other experts in order to provide additional expert views and/or judgements. All the experts involved in FSA study should have, as far as possible, a basic knowledge and understanding of the FSA methodology, as set out in the FSA Interim Guidelines.

~~4~~ 27 The experts to be involved should cover the widest possible range of knowledge relevant to the problem under consideration, including for instance:

.1 organizational and managerial aspects, e.g. pertinent to shipping companies;

.2 technical aspects, e.g. design, construction, operation and maintenance;

.3 legal, finance and insurance matters; and

.4 matters of concern to flag Administrations and port State controls.

~~5~~ 28 The names and credentials of the members of the team carrying out an FSA study and other experts involved should be included in an annex to the report containing the results of the study.

~~6~~ 29 Other experts in various fields ~~are likely to~~ may be involved when reviewing and discussing the results of the FSA study.

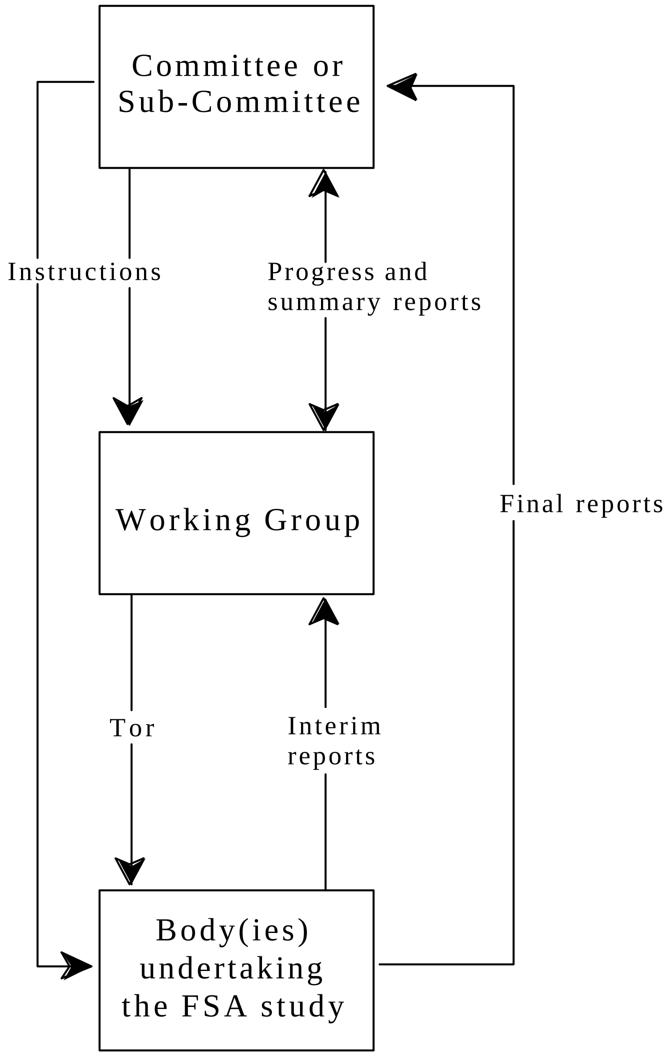

Committee or Sub-Committee
Instructions
Progress and summary reports
Working Group
Final reports
Tor
Interim reports
Body(ies) undertaking the FSA study

Figure 1

APPENDIX 2

~~DRAFT~~ GUIDANCE ON HUMAN RELIABILITY ANALYSIS (HRA) ~~WITHIN FORMAL SAFETY ASSESSMENT (FSA)~~

1. INTRODUCTION

1.1 Purpose of Human Reliability Analysis (HRA)

1.1.1 Those industries which routinely use quantitative risk assessment (QRA) to assess the frequency of system failures as part of the design process or ongoing operations management, have recognised that in order to produce valid results it is necessary to assess the contribution of the human element to system failure. The accepted way of incorporating the human element into QRA and FSA studies is through the use of human reliability analysis (HRA).

1.1.2 HRA was developed primarily for the nuclear industry. Using HRA in other industries requires that the techniques be appropriately adapted. For example, because the nuclear industry has many built-in automatic protection systems, consideration of the human element can be legitimately delayed until after consideration of the overall system performance. Onboard ship, the human has more degrees of freedom to disrupt system performance. Therefore, a high-level task analysis needs to be considered at the outset of an FSA.

1.1.3 HRA is a process, which comprises a set of activities and the potential use of a number of techniques depending on the overall objective of the analysis. HRA may be performed on a qualitative or quantitative basis depending on the level of FSA being undertaken. If a fully quantitative analysis is required then Human Error Probabilities can be derived in order to fit into quantified system models such as fault and event trees. However in many instances a qualitative analysis may be sufficient. The HRA process usually consists of the following stages:

.1 identification of key tasks;
.2 task analysis of key tasks;
.3 human error identification;
.4 human error analysis; and
.5 human reliability quantification.

1.1.4 Where a fully-quantified FSA approach is required, HRA can be used to develop a set of Human Error Probabilities (HEPs) for incorporation into probabilistic risk assessment. However, this aspect of HRA can be over-emphasised. Experienced practitioners admit that most benefit is derived from the early, qualitative stages of task analysis and human error identification. Effort expended in these areas pays dividends because an HRA exercise (like an FSA study) is successful only if the correct areas of concern have been chosen for investigation.

1.1.5 It is also necessary to bear in mind that the data available for the last stage of HRA, human reliability quantification, is currently limited. Although several human error databases have been built up, the data contained in them is only marginally relevant to the maritime industry. In some cases where an FSA requires quantitative results from the HRA, expert judgement may be the most appropriate method for deriving suitable data. Where expert judgement is used, it is important that the judgement can be properly justified as required by Annex 2 of the FSA Interim Guidelines: Standard Format for Reporting Trial Applications of the Formal Safety Assessment.

1.2 Scope of the HRA Guidance

1.2.1 Figure 1 shows how the HRA Guidance fits into the FSA process developed for the FSA ~~Interim~~ Guidelines. For ease of reference, the numbering system used in the FSA ~~Interim~~ Guidelines has been maintained in this document.

1.2.2 The amount of detail provided here is at a similar level to that given in the FSA ~~Interim~~ Guidelines, i.e. it states what should be done and what considerations should be taken into account. Details of some techniques used to carry out the process are provided in the appendices of this document.

1.2.3 The sheer volume of information about this topic prohibits the provision of in-depth information: there are numerous HRA techniques, and task analysis is a framework encompassing dozens of techniques. Table 1 lists the main references which could be pursued.

1.2.4 As with FSA, HRA can be applied to the design, construction, maintenance and operations of a ship.

1.3 Application

1.3.1 It is intended that this guidance should be used wherever an FSA is conducted on a system which involves human action or intervention which affects system performance.

2. BASIC TERMINOLOGY

Error Producing Condition : Factors that can have a negative effect on human performance.

Human Error : A departure from acceptable or desirable practice on the part of an individual or group of individuals that can result in unacceptable or undesirable results.

Human Error Recovery : The potential for the error to be recovered, either by the individual or by another person, before the undesired consequences are realised.

Human Error Consequence : The undesired consequences of human error.

Human Error Probability : Defined as follows:

$$HEP = \frac{\textit{Number of human errors that have occurred}}{\textit{Number of opportunities for human error}}$$

Human Reliability : The probability that a person: (1) correctly performs some system-required activity in a required time period (if time is a limiting factor) and (2) performs no extraneous activity that can degrade the system. *Human unreliability* is the opposite of this definition.

Performance Shaping Factors : Factors that can have a positive or negative effect on human performance.

Task analysis : A collection of techniques used to compare the demands of a system with the capabilities of the operator, usually with a view to improving performance, e.g. by reducing errors.

3. METHODOLOGY

3.1 HRA can be considered to fit into the overall FSA process in the following way:

1. Identification of key human tasks consistent with section 4 of the FSA ~~Interim~~ Guidelines;

2. Risk assessment, including a detailed task analysis, human error analysis and human reliability quantification consistent with section 5 of the FSA ~~Interim~~ Guidelines;

3. Risk control options consistent with section 6 of the FSA ~~Interim~~ Guidelines;

4. Cost benefit assessment (refer directly to section 7 of the FSA ~~Interim~~ Guidelines); and

5. Recommendations for decision making (refer directly to section 8 of the FSA ~~Interim~~ Guidelines).

4. HRA STEP 1 - IDENTIFICATION OF HAZARDS

4.1 Scope

4.1.1 The purpose of this step is to identify key potential human interactions which if not performed correctly could lead to system failure. This is a broad scoping exercise where the aim is to identify areas of concern (e.g. whole tasks or large subtasks) requiring further investigation. The techniques used here are the same as those used in Step 2, but in Step 2 they are used much more rigorously.

4.1.2 Human hazard identification is the process of systematically identifying the ways in which human error can contribute to accidents during normal and emergency operations. As they are detailed in the section 4.2.2 of the FSA ~~Interim~~ Guidelines, standard FSA techniques such as Hazard and Operability (HazOp) study and Failure Mode and Effects Analysis (FMEA) can, and are, used for this purpose. Additionally it is strongly advised that a high-level functional task analysis is also carried out. This section discusses those techniques which were developed solely to address human hazards.

4.2 Methods for hazard identification

4.2.1 In order to carry out a human hazard analysis, it is first necessary to model the system in order to identify the normal and emergency operating tasks that are carried out by the crew. This is achieved by the use of a high-level task analysis (as described in ~~appendix~~ table 2), which identifies the main human tasks in terms of operational goals. Developing a task analysis can utilise a range of data collection techniques e.g. interviews, observation, critical incident, many of which can be used to directly identify key tasks. Additionally, there are many other sources of information which may be consulted including design information, past experience, normal and emergency operating procedures, etc.

4.2.2 At this stage, it is not necessary to generate a lot of detail. The aim is to identify those key human interactions which require further attention. Therefore, once the main tasks, subtasks and their associated goals have been listed, the potential contributors to human error of each task need to be identified together with the potential hazard arising. There are a number of techniques which may be utilised for this purpose including: human error HazOp, Hazard Checklists etc. An example of human-related hazards identifying a number of different potential contributors to sub-standard performance is included in ~~appendix~~ table 3.

4.2.3 For each task and sub-task identified in section 4.2.2, the associated hazards should be ranked as described in order of their criticality in the same manner discussed in section 4.2.1 of the FSA ~~Interim~~ Guidelines.

4.3 Results

4.3.1 The output from step 1 is a set of activities (tasks and subtasks) with a ranked list of hazards associated with each activity. As this list needs to be coupled with the FSA list, it should be produced in the same format as stipulated in the FSA ~~Interim~~ Guidelines. Only the top few hazards for critical tasks are subjected to risk assessment, less critical tasks are not examined further.

5. HRA STEP 2 - RISK ASSESSMENT

5.1 Scope

5.1.1 The purpose of step 2 is to identify those areas where the human element poses a high risk to system safety and to evaluate the factors influencing the level of risk.

5.2 Detailed task analysis

5.2.1 At this stage, the key tasks are subjected to a Detailed Task ~~Analysis – see appendix 2 for details~~. Where the tasks involve more decision-making than action, it may be more appropriate to carry out a cognitive task analysis. ~~Appendix~~ Table 2 outlines Extended Task Analysis which was developed for analysing decision-making tasks.

5.2.2 The task analysis should be developed until all critical subtasks have been identified. The level of detail required is that which is appropriate for the criticality of the operation under investigation. A good general rule is that the amount of detail required should be sufficient to give the same degree of understanding as that provided by the rest of the FSA exercise.

5.3 Human error analysis

5.3.1 The purpose of human error analysis is to produce a list of potential human errors that can lead to the undesired consequence that is of concern. To help with this exercise, some examples of typical human errors are included in figure 2.

5.3.2 Once all potential errors have been identified, they are typically classified along the following lines. This classification allows the identification of a critical subset of human errors that must be addressed:

.1 the supposed cause of the human error;

.2 the potential for error-recovery, either by the operator or by another person (this includes consideration of whether a single human error can result in undesired consequences); and

.3 the potential consequences of the error.

5.3.3 Often, a qualitative analysis should be sufficient. A simple qualitative assessment can be made using a recovery/consequence matrix such as that illustrated in figure 3. Where necessary, a more detailed matrix can be developed using a scale for the likely consequences and levels of recovery.

5.4 Human error quantification

5.4.1 This activity is undertaken where a probability of human error (HEP) is required to input into a quantitative FSA. Human error quantification can be conducted in a number of ways.

5.4.2 In some cases, because of the difficulties of acquiring reliable human error data for the maritime industry, expert judgement techniques may need to be used for deriving a probability for human error. Expert judgement techniques can be grouped into four categories:

.1 paired comparisons;

.2 ranking and rating procedures;

.3 direct numerical estimation; and

.4 indirect numerical estimation.

It is particularly important that experts are provided with a thorough task definition. A poor definition invariably produces poor estimates.

5.4.3 Absolute Probability Judgement (APJ) is a good direct method. It can be used in various forms, from the single expert assessor, to large groups of individuals whose estimates are mathematically aggregated (see Table 4). ~~APJ is detailed in appendix 4.~~ Other techniques which focus on judgements from multiple experts include: brainstorming; consensus decision-making; Delphi; and the Nominal Group technique.

5.4.4 Alternatives to expert opinion are historic data (where available) and generic error probabilities. Two main methods for HRA which have databases of human error probabilities (mainly for the Nuclear Industry) are the Technique for Human Error Rate Prediction (THERP) and Human Error Assessment and Reduction Technique (HEART) (See Table 4). ~~These are detailed in appendix 4.~~

5.4.5 Technique for Human Error Rate Prediction (THERP)

THERP was developed by Swain and Guttmann (1983) of Sandia National Laboratories for the US Nuclear Regulatory Commission, and has become the most widely used human error quantitative prediction technique. THERP is both a human reliability technique and a human error databank. It models human errors using probability trees and models of dependence, but also considers performance shaping factors (PSFs) affecting action. It is critically dependent on its database of human error probabilities. It is considered to be particularly effective in quantifying errors in highly proceduralised activities.

5.4.6 Human Error Assessment and Reduction Technique (HEART)

HEART is a technique developed by Williams (1985) that considers particular ergonomics, task and environmental factors that adversely affect performance. The extent to which each factor independently affects performance is quantified, and the human error probability is calculated as a function of the product of those factors identified for a particular task.

5.4.7 HEART provides specific information on remedial risk control options to combat human error. It focuses on five particular causes and contributions to human error: impaired system knowledge; response time shortage; poor or ambiguous system feedback; significant judgement required of operator; and, the level of alertness resulting from duties, ill-health or the environment.

5.4.8 When applying human error quantification techniques, it is important to consider the following:

1. Magnitudes of human error are sufficient for most applications. A 'gross' approximation of the human error magnitude is sufficient. The derivation of HEPs may be influenced by modelling and quantitative uncertainties. A final sensitivity analysis should be presented to show the effect of uncertainties on the estimated risks.

2. Human Error Quantification can be very effective when used to produce a comparative analysis rather than an exact quantification. Then human error quantification can be used to support the evaluation of various risk control options.

3. The detail of quantitative analysis should be consistent with the level of detail of the FSA model. The HRA should not be more detailed than the technical elements of the FSA. The level of detail should be selected based upon the contribution of the activity to the risk, system or operation being analysed.

4. The human error quantification tool selected, should fit the needs of the analysis. There are a significant number of human error quantification techniques available. The selection of a technique should be assessed for consistency, usability, validity of results, usefulness, effective use of resources for the HRA, and the maturity of the technique.

5.5 Results

5.5.1 The output from this step comprises:

.1 an analysis of key tasks;

.2 an identification of human errors associated with these tasks; and

.3 an assessment of human error probabilities (optional).

5.5.2 These results should then be considered in conjunction with the high-risk areas identified in section 5.4 of the FSA Interim Guidelines.

6. HRA STEP 3 - RISK CONTROL OPTIONS

6.1 Scope

6.1.1 The purpose of step 3 is to consider how the human element is considered within the evaluation of technical, human, work environment, personnel and management related risk control options.

6.2 Application

6.2.1 The control of risks associated with the human interaction with a system can be approached in the same way as for the development of other risk control measures. Measures can be specified in order to:

.1 reduce the frequency of failure;

.2 mitigate the effects of failure;

.3 alleviate the circumstances in which failures occur; and

.4 mitigate the consequence of accidents.

6.2.2 Proper application of HRA can reveal that technological innovations can also create problems which may be overlooked by FSA evaluation of technical factors only. A typical example of this is the creation of long periods of low workload when a high degree of automation is used. This in turn can lead to an inability to respond correctly when required or even to the introduction of 'risk taking behaviour' in order to make the job more interesting.

6.2.3 When dealing with risk control concerning human activity it is important to realise that more than one level of risk control measure may be necessary. This is because human involvement spans a wide range of activities from day-to-day operations through to senior management levels. Secondly, it must also be stressed that a basic focus on good system design utilising ergonomics and human factors principles is needed in order to achieve enhanced operational safety and performance levels.

6.2.4 In line with figure 2 of the FSA ~~Interim~~ Guidelines, risk control measures for human interactions can be categorised into four areas as follows: (1) Technical/Engineering Sub-System, (2) Working Environment, (3) Personnel Sub-System and (4) Organisational/Management Sub-System. A description of the issues that may be considered within each of these areas is given in figure 4.

6.2.5 Once the risk control measures have been initially specified, it is important to reassess human intervention in the system in order to assess whether any new hazards have been introduced. For example, if a decision had been taken to automate a particular task, then the new task would need to be re-evaluated.

6.3 Results

6.3.1 The output from this step comprises a range of risk control options categorised into 4 areas as presented in figure 4.

6.3.2 This categorisation eases the integration of human related risk into section 6.5.1 of the FSA ~~Interim~~ Guidelines.

7. HRA STEP 4 - COST BENEFIT ASSESSMENT

7.1 No specific human reliability analysis guidance for this section is required. See section 7 of the FSA ~~Interim~~ Guidelines.

8. HRA STEP 5 - RECOMMENDATIONS FOR DECISION MAKING

8.1 Judicious use of the results of the HRA study should contribute to a set of balanced decisions and recommendations of the whole FSA study. The process for this section is described in section 8 of the FSA ~~Interim~~ Guidelines.

Figure 1: Block diagram integrating HRA techniques into the IMO FSA ~~Interim~~ Guidelines

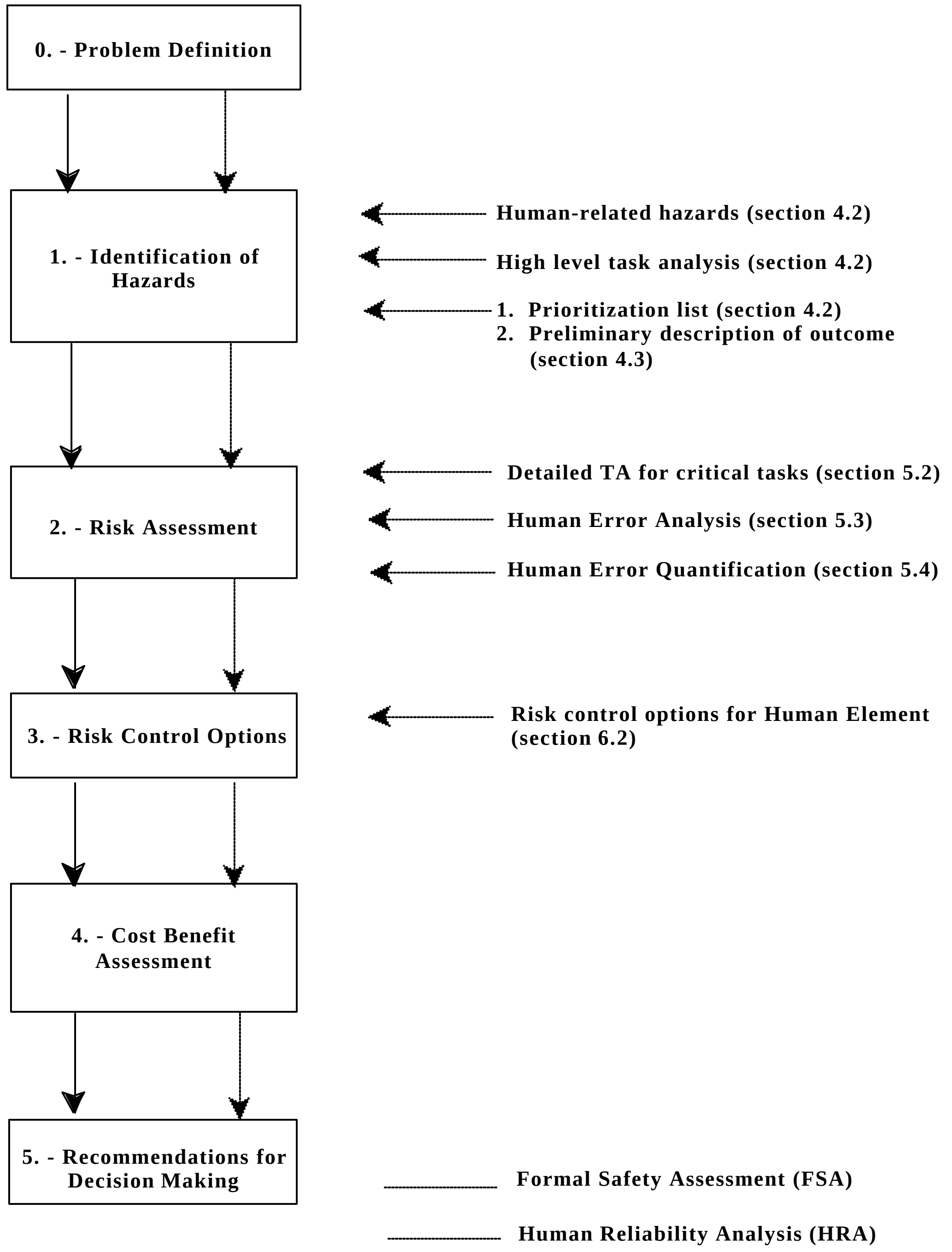


Figure 2: Typical human errors

Physical Errors	*Mental Errors*
Action omitted Action too much/little Action in wrong direction Action mistimed Action on wrong object	Lack of knowledge of system/situation Lack of attention Failure to remember procedures Communication breakdowns Miscalculation

Figure 3: Recovery/consequence matrix

Consequence		Recovery: High	Recovery: Low
	High	**May need to consider**	**MUST CONSIDER**
	Low	**No need to consider**	**May need to consider**

Figure 4: Examples of risk control option

Technical/Engineering Sub-System
- ergonomic design of equipment and work spaces
- good layout of bridge, machinery spaces
- ergonomic design of the man-machine interface/ human computer interface
- specification of information requirements for the crew to perform their tasks
  clear labelling and instructions on the operation of ship systems and control/communications equipment

Working Environment
- ship stability, effect on crew of working under conditions of pitch/roll
- weather effects, including fog, particularly on watch-keeping or external tasks
- ship location, open sea, approach to port, etc.
- appropriate levels of lighting for operations and maintenance tasks, and for day and night time operations
- consideration of noise levels (particularly for effect on communications)
- consideration of temperature and humidity on task performance
- consideration of the effects of vibration on task performance

Personnel Sub-System
- development of appropriate training for crew members
- crew levels and make up
- language and cultural issues
- workload assessment (both too much and too little workload can be problematic)
- motivational and leadership issues

Organisational/Management Sub-System
- development of organisation policies on recruitment, selection, training, crew levels and make up, competency assessment, etc.
- development of operational and emergency procedures (including provision for tug and salvage services)
- use of safety management systems
- provision of weather forecasting/routeing services

~~APPENDIX 1: HRA~~ TABLE 1: REFERENCES

1. Advisory Committee on the Safety of Nuclear Installations (1991*) Human Factors Study Group Second Report: Human reliability assessment - a critical overview*.
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~~APPENDIX~~ TABLE 2: SUMMARY OF TASK ANALYSIS TYPES

1. High-Level Task Analysis

High-level task analysis here refers to the type of task analysis which allows an analyst to gain a broad, but shallow, overview of the main functions which need to be performed, to accomplish a particular task.

High-level task analysis is undertaken in the following way:

- describe all operations within the system in terms of the tasks required to achieve a specific operational goal
- consider goals associated with normal operations, emergency procedures, maintenance and recovery measures

The analysis is recorded either in an hierarchical format or in tabular form.

2. Detailed Task Analysis

Detailed task analysis is undertaken to identify:

- the overall task (or job) that is done
- subtasks
- all of the people who contribute to the task, and their interactions
- how the work is done i.e. the working practices in normal and emergency situations
- any controls, displays, tools, etc. which are used
- factors which influence performance

There are many task analysis techniques - Kirwan and Ainsworth (1992) list more than twenty. They note that the most widely used, hierarchical task analysis (HTA) can be used as a framework for applying other techniques:

- Data collection techniques, e.g. activity sampling, critical incident, questionnaires
- Task description techniques, e.g. charting and network techniques, tabular task analysis.
- Tasks simulation methods, e.g. computer modelling and simulation.
- Task behaviour assessment methods, e.g. management and oversight risk trees
- Task requirement evaluation methods, e.g. ergonomics checklists

3. Extended Task Analysis (XTA)

Traditional task analysis was designed for investigating manual tasks, and is not so useful for analysing intellectual tasks, e.g. navigation decisions. Extended Task Analysis or other cognitive task analyses (see Annett and Stanton, 1998) can be used where the focus is less on what actions are performed, and more on understanding the rationale for the decisions that are taken.

XTA is used to map out the logical bases of the decision-making process which underpin the task under examination. The activities which comprise XTA techniques are described in Johnson and Johnson (1987). In summary, they are:

- Interview. The interviewer asks about the conditions which enable or disable certain actions to be performed, and how a change in the conditions affects those choices. The interviewer examines the individual's intentions to make sure that all relevant aspects of the situation have been taken into account. This enables the analyst to build up a good understanding of what the individual is doing and why, and how it would change under varying conditions.

- Qualitative analysis of data. The interview is tape-recorded, transcribed and subsequently analysed. Methods for analysing qualitative data are well-established in social science and more recently utilised in safety engineering. The technique (called Grounded Theory) is described in detail by Pidgeon, *et al.* (1991).

- Representation of the analysis in an appropriate format. The representation scheme used in XTA is called systemic grammar networks - a form of associative network - see Johnson and Johnson (1987).

- Validation activities, e.g. observation, hypothesis

~~APPENDIX~~ TABLE 3: EXAMPLES OF HUMAN-RELATED HAZARDS

Human error occurs onboard ship when a crew member's ability falls below what is needed to successfully complete a task. Whilst this may be due to a lack of ability, more commonly it is because the existing ability is hampered by adverse conditions. Below are some examples (not complete) of personal factors and unfavourable conditions which constitute hazards to optimum performance. A comprehensive examination of all human-related hazards should be performed. During the 'design stage' it is typical to focus mainly on task features and on board working conditions as potential human-related hazards.

Personal factors

- Reduced ability, e.g. reduced vision or hearing
- Lack of motivation, e.g. because of a lack of incentives to perform well
- Lack of ability, e.g. lack of seamanship, unfamiliarity with vessel, lack of fluency of the language used onboard
- Fatigue, e.g. because of lack of sleep or rest, irregular meals
- Stress

Organizational and leadership factors

- Inadequate vessel management, e.g. inadequate supervision of work, lack of co-ordination of work, lack of leadership
- Inadequate ship owner management by, e.g. inadequate routines and procedures, lack of resources for maintenance, lack of resources for safe operation, inadequate follow-up of vessel organisation
- Inadequate manning, e.g. too few crew, untrained crew
- Inadequate routines, e.g. for navigation, engine room operations, cargo handling, maintenance, emergency preparedness

Task features

- Task complexity and task load i.e. too high to do comfortably, or too low causing boredom
- Unfamiliarity of the task
- Ambiguity of the task goal
- Different tasks competing for attention

Onboard working conditions

- Physical stress from, e.g. noise, vibration, sea motion, climate, temperature, toxic substances, extreme environmental loads, night-watch
- Ergonomic conditions, e.g. inadequate tools, inadequate illumination, inadequate or ambiguous information, badly-designed human-machine interface
- Social climate, e.g. inadequate communication, lack of co-operation
- Environmental conditions, e.g. restricted visibility, high traffic density, restricted fairway

~~APPENDIX~~ TABLE 4: SUMMARY OF HUMAN ERROR ANALYSIS TECHNIQUES

The two main HRA quantitative techniques (HEART and THERP) are outlined below. CORE-DATA provides data on generic probabilities. As the data from all of these sources is based on non-marine industries, it needs to be used with caution. A good alternative is to use expert judgement, and one technique for doing this is Absolute Probability Judgement.

1. Absolute Probability Judgement (APJ)

APJ refers to a group of techniques that utilise expert judgement to develop human error probabilities (HEPs) detailed in Kirwan (1994) and Lees (1996). These techniques are used when no relevant data exists for the situation in question, making some form of direct numerical estimation the only way of developing values for HEPs.

There are a variety of techniques available. This gives the analyst some flexibility in accommodating different types of analysis. Most of the techniques avoid potentially detrimental group influences such as group bias. Typically the techniques used are: the Delphi technique, the Nominal Group Technique and Paired Comparisons. The number and type of experts that are required to participate in the process are similar to that required for Hazard Identification techniques such as HazOp.

Paired Comparisons is a significant, expert judgement technique. Using this technique, an individual makes a series of judgements about pairs of tasks. The results for each individual are analysed and the relative values for HEPs for the tasks derived. Use of the technique rests upon the ability to include at least two tasks with known HEPs. CORE-DATA and data from other industries may be useful.

The popularity of these techniques has reduced in recent times, probably due to the requirement to get the relevant groups of experts together. However, these techniques may be very appropriate for the maritime industry.

2. Technique for Human Error Rate Prediction (THERP)

THERP is one of the best known and most often utilised human reliability analysis techniques. First sight of the technique can be rather daunting due to the volume of information provided. This is because it is a comprehensive methodology covering task analysis, human error identification, human error modelling and human error quantification. However, it is best known for its human error quantification aspects, which includes a series of human error probability (HEP) data tables and data quantifying the effects of various performance shaping factors (PSFs). The data presented is generally of a detailed nature and so is not readily transferable to the marine environment.

THERP contains a dependence model which is used to model the dependence relationship between errors. For example, the model could be used to assess the dependence between the helmsman making an error and the bridge officer noticing it. Operational experience does show that there are dependence effects between people and between tasks. Whilst this is the only human error model of its type, it has not been comprehensively validated.

A full THERP analysis can be resource-intensive due to the level of detail required to utilise the technique properly. However, the use of this technique forces the analyst to gain a detailed appreciation of the system and of the human error potential. THERP models the human as any other sub-system in the FSA modelling process. The steps are as follows:

1. identify all the systems in the operation that are influenced and affected by human operations;

2. compile a list and analyse all human operations that affect the operations of the system by performing a detailed task analysis;

3. determine the probabilities of human errors through error frequency data and expert judgements and experiences; and

4. determine the effects of human errors by integrating the human error into the PRA modelling procedure.

THERP includes a set of performance shaping factors (PSFs) that influence the human errors at the operator level. These performance factors include experience, situational stress factors, work environment, individual motivation, and the human-machine interface. The PSFs are used as a basis for estimating nominal values and value ranges for human error.

There are advantages to using THERP. First it is a good tool for relative risk comparisons. It can be used to measure the role of human error in an FSA and to evaluate risk control options not necessarily in terms of a probability or frequency, but in terms of risk magnitude. Also, THERP can be used with the standard event-tree/fault-tree modelling approaches that are sometimes preferred by FSA practitioners. THERP is a transparent technique that provides a systematic, well-documented approach to evaluating the role of human errors in a technical system. The THERP database can be used through systematic analysis or, where available, external human error data can be inserted.

3. Human Error Assessment Reduction Technique (HEART)

HEART is best known as a relatively simple way of arriving at human error probabilities (HEPs). In the U.K. it is a commonly used technique. The basis of the technique is a database of nine generic task descriptions and an associated human error probability. The analyst matches the generic task description to the task being assessed and then modifies the generic human error probability according to the presence and strength of the identified error producing conditions (EPCs). EPCs are conditions that increase the order of magnitude of the error frequency or probability measurements, similar in concept to PSFs in THERP. A list of EPCs is supplied as part of the technique, but it is up to the analyst to decide on the strength of effect, for the task in question.

Whilst the generic data is mainly derived from the nuclear industry, HEART does appear amenable to application within other industries. It may be possible to tailor the technique to the marine environment by including new EPCs such as weather. However, it needs careful application to avoid ending up with very conservative estimates of HEPs.

4. CORE-DATA

CORE-DATA is a database of human error probabilities. Access to the database is available through the University of Birmingham in the U.K. The database has been developed as a result of sponsorship by the UK Health and Safety Executive with support from the nuclear, rail, chemical, aviation and offshore industries and contains up to 300 records as of January 1999.

Each record is a comprehensive presentation of information including, e.g. a task summary, industry origin, country of origin, type of data collection used, a database quality rating, description of the operation, performance shaping factors, sample size and HEP.

As with all data from other industries, care needs to be taken when transferring the data to the maritime industry. Some of the offshore data may be the most useful.

APPENDIX ~~2~~3

EXAMPLES OF HAZARDS

1 SHIPBOARD HAZARDS TO PERSONNEL

- asbestos inhalation
- burns from caustic liquids and acids
- electric shock and electrocution
- falling overboard
- pilot ladder/pilot hoist operation

2 HAZARDOUS SUBSTANCES ON BOARD SHIP

Accommodation areas:
- combustible furnishings
- cleaning materials in stores
- oil/fat in galley equipment

Deck Areas:
- cargo
- paint, oils, greases etc. in deck stores

Machinery spaces:
- cabling
- fuel and diesel oil for engines, boilers and incinerators
- fuel, lubricating and hydraulic oil in bilges, savealls, etc.
- refrigerants
- thermal heating fluid systems

3 POTENTIAL SOURCES OF IGNITION

General
- electrical arc
- friction
- hot surface
- incendive spark
- naked flame
- radio waves

Accommodation areas (including bridge):
- electronic navigation equipment
- laundry facilities - irons, washing machines, tumble driers, etc.

Deck areas:
- deck lighting
- funnel exhaust emissions
- hot work sparking

Machinery spaces:
- air compressor units
- generator engine exhaust manifold

4 HAZARDS EXTERNAL TO THE SHIP

- storms
- lightning
- uncharted submerged objects
- other ships

APPENDIX 4

HAZARD IDENTIFICATION TECHNIQUES

1 Fault Tree Analysis

1.1 A Fault Tree is a logic diagram showing the causal relationship between events which singly or in combination occur to cause the occurrence of a higher level event. It is used in Fault Tree Analysis to determine the probability of a top event, which may be a type of accident or unintended hazardous outcome. Fault Tree Analysis can take account of common cause failures in systems with redundant or standby elements. Fault Trees can include failure events or causes related to human factors.

1.2 The development of a Fault Tree is by a top-down approach, systematically considering the causes or events at levels below the top level. If two or more lower events need to occur to cause the next higher event, this is shown by a logic `and' gate. If any one of two or more lower events can cause the next higher event, this is shown by a logic `or' gate. The logic gates determine the addition or multiplication of probabilities (assuming independence) to obtain the values for the top event.

2 Event Tree Analysis

2.1 An Event Tree is a logic diagram used to analyse the effects of an accident, a failure or an unintended event. The diagram shows probability or frequency of the accident linked to those safeguard actions required to be taken after occurrence of the event to mitigate or prevent escalation.

2.2 The probabilities of success or failure of these actions are analysed. The success and failure paths lead to various consequences of differing severity or magnitude. Multiplying the likelihood of the accident by the probabilities of failure or success in each path gives the likelihood of each consequence.

3 Failure Mode and Effect Analysis (FMEA)

3.1 FMEA is a technique in which the system to be analysed is defined in terms of functions or hardware. Each item in the system is identified at a required level of analysis. This may be at a replaceable item level. The effects of item failure at that level and at higher levels are analysed to determine their severity on the system as a whole. Any compensating or mitigating provisions in the system are taken account of and recommendations for the reduction of the severity are determined. The analysis indicates single failure modes which may cause system failure.

4 Hazard and Operability Studies (HAZOP)

4.1 These studies are carried out to analyse the hazards in a system at progressive phases of its development from concept to operation. The aim is to eliminate or minimise potential hazards.

4.2 Teams of safety analysts and specialists in the subject system, such as designers, constructors and operators are formally constituted. The team members may change at successive phases depending on the expertise required. In examining designs they systematically consider deviations from the intended functions, looking at causes and effects. They record the findings and recommendations and follow up actions required.

APPENDIX 5 (From MSC 72/16, annex 3)

INITIAL RANKING OF ACCIDENT SCENARIOS

At the end of Step 1, hazards are to be prioritised and scenarios ranked. Scenarios are typically the sequence of events from the initiating event up to the consequence, through the intermediate stages of the scenario development. (~~MSC/Circ.829~~ see paragraph 4.4.1 of the FSA Guidelines).

~~If a scenario ranking is carried out, this ranking should, as far as practical, be consistent with the risk acceptance criteria. Note, however, that an FN diagram and a risk matrix commonly used for ranking purposes do not use the same format, MSC/Circ.829 , Figure 3. The risk matrix is on the format of fN diagram (probability of exactly N fatalities as opposed to N or more fatalities). Only negligible risk contributions should be excluded from further analysis.~~

To facilitate the ranking and validation of ranking (~~e.g. by the hazid team~~), it is generally recommended to define consequence and probability indices on a ~~strictly~~ logarithmic scale. The reason for the logarithmic scale, is that

Risk = Probability x Consequence
Log(Risk) = log (Probability) + log (Consequence)

A risk index may therefore be established by adding the probability/frequency and consequence indices.

The following ~~consequence~~ severity index (s) is suggested

~~Consequence~~ Severity Index				
SI	SEVERITY	EFFECTS ON HUMAN SAFETY	EFFECTS ON SHIP	S (Equivalent fatalities)
1	Minor	Single or minor injuries	Local equipment damage	0.01
2	Significant	Multiple or severe injuries	Non-severe ship damage	0.1
3	Severe	Single fatality or multiple severe injuries	Severe damage	1
4	Catastrophic	Multiple fatalities	Total loss	10

The following probability/frequency index (FI) is suggested. ~~The wording is identical to MSC/Circ.829 , Figure 3.~~

Frequency Index			
FI	FREQUENCY	DEFINITION	F (per ship year)
7	Frequent	Likely to occur once per month on one ship	10
5	Reasonably probable	Likely to occur once per year in a fleet of 10 ships, i.e. likely to occur a few times during the ship's life	0.1
3	Remote	Likely to occur once per year in a fleet of 1000 ships, i.e. likely to occur in the total life of several similar ships	10^{-3}
1	Extremely remote	Likely to occur once in 10 years in a fleet of 1000 ships.	10^{-5}

By deciding to use a logarithmic scale, the Risk index for ranking purposes may be calculated as

RI = FI + SI

E.g. An event rated “remote” (FI=3) with severity “Significant” (SI=2) would have RI=5.

The resulting risk matrix ~~(risk indices in bold) suggested would be~~ is:

Risk Matrix						
		SEVERITY (SI)				
		1	2	3	4	
FI	FREQUENCY	Minor	Significant	Severe	Catastrophic	
7	Frequent	**8**	**9**	**10**	**11**	
6		**7**	**8**	**9**	**10**	
5	Reasonably probable	**6**	**7**	**8**	**9**	
4		**5**	**6**	**7**	**8**	
3	Remote	**4**	**5**	**6**	**7**	
2		**3**	**4**	**5**	**6**	
1	Extremely remote	**2**	**3**	**4**	**5**	

Negligible scenarios may thus be defined by comparison with the relevant FN-diagram. Furthermore, the ranking could be compared with known risks by observing that

$$Risk = Probability \ x \ Consequence$$
$$Risk = 10^{(FI-6)} \ x \ 10^{(SI-3)} \ \cancel{= 10^{FI+RI-9}} \ \cancel{= 10^{RI-9}}$$
$$Risk = 10^{(RI-9)}$$

~~This way~~ The quality of the ranking could be verified against known risks, as a ranking will involve both unknown risks and risks that have been quantified in the past.

APPENDIX ~~3~~ 6

MEASURES AND TOLERABILITY OF RISKS

1 There are two fundamental measures of risk, individual risk and societal risk. It is necessary for the risk to be both tolerable to the individual and tolerable to society. Individual risk can be regarded as the risk to an individual in isolation while societal risk is the risk to society of a major accident. There is a clear perception in society that a single accident that kills 1,000 people is worse than 1,000 accidents that kill a single person. Therefore the tolerable level of societal risk is usually lower than the tolerable level of individual risk.

2 Individual risk is usually assessed by some form of a criticality matrix where the risk is assessed against frequency of occurrence (ranging from extremely remote to frequent) and severity of outcome (ranging from insignificant to catastrophic). Societal risk is usually assessed by a technique such as an FN curve where the acceptable level of frequency of an accident (F) is plotted against the number of people killed by the accident (N).

3 When each risk assessment is made, it will be necessary also to determine which assessment method should be used. Generally, accidents that cause one or two fatalities are best assessed by individual risk considerations, while accidents that cause the loss of a crew or the passengers are best assessed by societal risk considerations.

4 Whichever assessment method is used, the uncertainties of quantitative risk assessment must be balanced against the potential risk reduction. It is necessary to consider the uncertainty in the process in order to avoid premature judgements about the benefits of a particular Risk Control Option.

5 The current best practice is to recognise that there are three levels of risk: Intolerable, As Low As Reasonably Practicable (ALARP) and Negligible.

6 "Intolerable" means that the risk cannot be justified except in extraordinary circumstances, "Negligible" that the risk has been made so small that no further precaution is necessary, and "ALARP" that the risk falls between these two states.

7 The risk when travelling on a ferry should therefore be made "ALARP". There are no exceptional benefits to a passenger to allow an "intolerable" risk and sea travel can clearly never be made so safe that the risk is "negligible" and no precautions need to be made.

8 The extent to which risk exposure is involuntary (as opposed to voluntary) may also be relevant in determining the acceptability of risk. For example, a lower level of risk might be appropriate for people living near a port and unaware of the risks that shipping operations impose upon them, compared with the risks experienced by crew members who choose to continue their employment in a particular shipping trade.

APPENDIX ~~6~~7

**GUIDANCE ON THE USE OF
THE REGULATORY IMPACT DIAGRAM**

Introduction

1 FSA is a rational means for establishing regulatory requirements based upon a systematic assessment of maritime risks, and an evaluation of the costs and benefits of reducing risk to ensure an acceptable level of safety while maintaining an equitable commercial environment for international shipping. FSA is proactive, integrated, and above all based on risk evaluation and management in a transparent and justifiable manner thereby encouraging greater compliance with the maritime regulatory framework, in turn leading to improved safety and environmental protection. In other words, the effectiveness of any measures taken by the Organization towards improving safety, as may be assessed using FSA, is ultimately determined by the impact or influence these measures have on the behaviour of those involved in the shipping enterprise.

Influence

2 A number of influences affect safety in shipping. This would include the likelihood of human error, a function of the reliability of humans to act accordingly in the given circumstance(s). This reliability is influenced by, amongst other things: the organisational climate on board a vessel, the training and competence of the individuals involved and hardware factors such as equipment design and operability. If this influence is poor, human reliability may decrease. Conversely, a positive influence may improve reliability. These direct influences have, in turn, their own influences; some related to hardware, others to the operating climate. All are underpinned and influenced by the regulatory framework developed and adopted by: flag States, port States, coastal States etc, and, of course, the Organization.

Managing Human Factor Risk

3 Managing human reliability through ‘variation of influence’ is an option to reduce risk in shipping, particularly so in view of the assertion that up to 80% of all accidents at sea are attributable to human error. However, the different kinds of human error will undoubtedly have different underlying causes and influences. Any risk control measures adopted to address human reliability must similarly vary.

4 The Organization, through its Member Governments, uses its regulatory framework; SOLAS, MARPOL, STCW etc., to exert influence including over the individuals involved in the shipping industry. To efficiently enhance these influences, to improve human reliability, requires knowledge of the connection between those areas where the existing regulatory influence is strong and adequate, or where it is weak and inadequate. When compared with an understanding of where high-risk levels lie, the diagnosis of where to focus regulatory expenditure becomes clearer. In other words, to assist in effective decision making, the Organization requires evidence to identify regulations that target areas of need while drawing back in areas where the potential for risk reduction is less likely; to weaken the poor influences and enhance the positive. This requires, amongst other things, the effects of human reliability within the system to be assessed.

Risk Assessment

Traditional Approach

5 In the conduct of a marine FSA, the traditional approach to risk assessment is to develop a risk profile that is high level. As in all risk assessments, it is vital that this risk profile is created using the frequency and consequence approach generated by fault and event trees. However, fault and event trees use 'corrections' to account for the contribution made by the human element and are often incapable of displaying and linking different types of causal information. This is the area where the RID approach becomes complimentary to the risk profile

6 The RID is a method of modelling the network of influences on an event. These influences link failures at the operational level with their direct causes, and with the underlying organisational and regulatory influences. The approach is therefore capable of identifying all the influences (and therefore underlying causal information) that help explain why a marine risk profile may show high risk levels in one aspect (or even vessel type) and low risk level in another aspect. As the RID recognises that the risk profile is influenced by human, organisational, market hardware and regulations, it allows an holistic understanding of the problem area to be displayed in a hierarchical way.

Regulatory Impact Diagram (RID) Approach

7 The RID approach is derived from decision analysis and, being based on expert judgements, is particularly useful in situations for which there may be little, or no empirical data available. The technique is a variation of the 'influence diagram' methodology applied in risk management by other industrial sectors. This would include, for example, the nuclear industry, and offshore oil exploration and production industry – where it has been used in lifeboat evacuation assessment. The construction of a RID involves defining the target event – the accident - and describing the general setting and conditions, the associated influences, for example the quality of inspection and maintenance procedures, which lead up to the event. An example of a RID is illustrated in figure 1. In this case the influences on the event are modelled applying a hierarchy of 4 levels, that is :

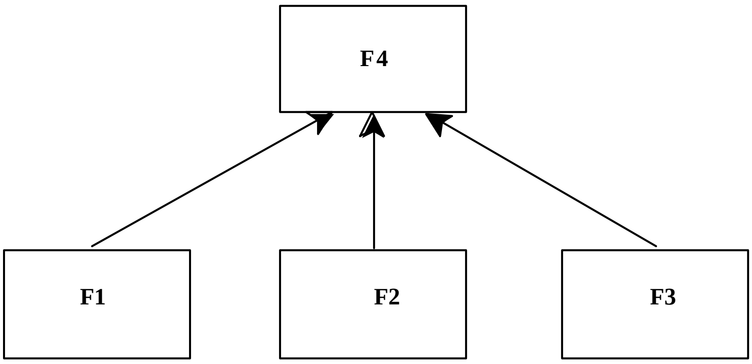
- a Direct Level (the direct causes of accidents, e.g. grounding, loss of hull integrity, etc.);
- an Organisational Level (the factors that influence the direct level);
- a Regulatory Level (the regulations and requirements that influence the shipping organisation);
- a Policy Level (the Codes and Conventions and political structure that influences national regulators).

With the influences identified, their impact is evaluated quantitatively, with the resulting values used to calculate, for example, human error probability. The construction and quantification of the RID is undertaken through interviews with subject matter experts, e.g., in the case of a marine FSA, masters, chief engineers, superintendents, regulators, technical specialists, human factors experts, and others.

Practical Application of RIDs in FSA

~~8 RIDs are not used in FSA Step 1. The generation of hazard information by brainstorming and other recognised means is undertaken~~.

~~4~~ 8 The diagram can be constructed by building the links from the policy level upwards through the regulation, organisation, direct and failure levels to arrive at the accident (or event). The weightings are then quantified from the top down, i.e. from the accident downwards to the policy level. At each point where a number of weightings converge on a factor to form a node, the sum of the weightings will equal one as shown in the following figure.



W1 + W2 + W3 = 1

Where W1, W2 and W3 are the weightings linking factors F1, F2 and F3 to factor F4.

9 The RID may become~~s~~ ~~of~~ useful in FSA Step 2. In parallel with the generation of human performance criteria developed applying the human reliability analysis (HRA) techniques ~~identified in the comprehensive IACS paper (MSC 71/14/1),~~ the RID structure(s) can be created ~~for the subject vessel type~~ from the human element data and wider information. Quantification of the RID then identifies the areas of strongest influence to the risk profile, i.e., whether positive or negative in terms of the impact on, for example, human reliability.

10 As the development of risk control measures is a Step 3 activity, the RID links the information in FSA Step 2 with FSA step 3. The relationships, once established and quantified, can then be used to investigate the effect that proposed Risk Control Options have on the risk level. The RID re-quantification to assess changes in influence is again complementary to the assessment of frequency/consequence reduction using the traditional fault and event tree approach. A more detailed description on the use of RIDs as part of the FSA process may be found in paper MSC 69/INF.14 sections 81-111 and MSC 71/WP.15/Add.1 Annex 6.

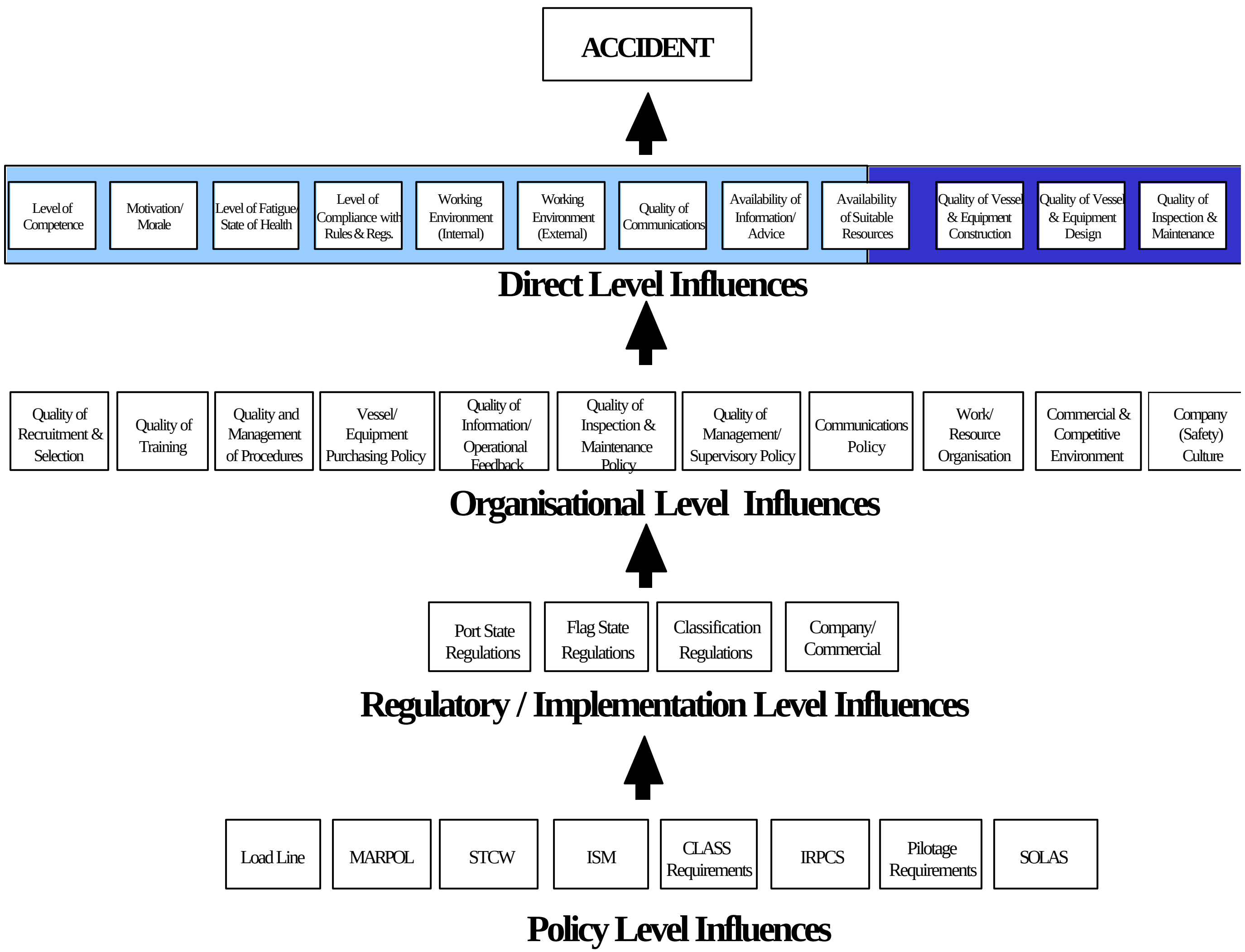
Conclusion

11 The risk benefit gained by the introduction of any new control measures is not an exact science, whatever approach to risk assessment is used. RIDs can be regarded as causal models which are useful for the successive decomposition of events, so that the impact of identified influencing factors in a particular event sequence can be studied. This information is complementary to the risk profile and provides a method to assess the impact of the factors with greatest influence on the Risk Contribution Tree and, when displayed in this way, is of assistance (alongside fault and event trees) in diagnosing the areas in which regulatory expenditure could be targeted in accordance with FSA Step 4.

= Primarily Human Influences

= Primarily Hardware Influences

Figure 1 - Example of RID



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APPENDIX ~~4~~8

ATTRIBUTES OF RISK CONTROL MEASURES

1 Category A attributes

1.1 **Preventive risk control** is where the risk control measure reduces the probability of the event.

1.2 **Mitigating risk control** is where the risk control measure reduces the severity of the outcome of the event or subsequent events, should they occur.

2 Category B attributes

2.1 **Engineering risk control** involves including safety features (either built in or added on) within a design. Such safety features are safety critical when the absence of the safety feature would result in an unacceptable level of risk.

2.2 **Inherent risk control** is where at the highest conceptual level in the design process, choices are made that restrict the level of potential risk.

2.3 **Procedural risk control** is where the operators are relied upon to control the risk by behaving in accordance with defined procedures.

3 Category C attributes

3.1 **Diverse risk control** is where the control is distributed in different ways across aspects of the system, whereas concentrated risk control is where the risk control is similar across aspects of the system.

3.2 **Redundant risk control** is where the risk control is robust to failure of risk control, whereas **single risk control** is where the risk control is vulnerable to failure of risk control.

3.3 **Passive risk control** is where there is no action required to deliver the risk control measure, whereas **active risk control** is where the risk control is provided by the action of safety equipment or operators.

3.4 **Independent risk control** is where the risk control measure has no influence on other elements.

3.5 **Dependent risk control** is where one risk control measure can influence another element of the risk contribution tree.

3.6 **Involved human factors** is where human action is required to control the risk but where failure of the human action will not in itself cause an accident or allow an accident sequence to progress. **Critical human factors** is where human action is vital to control the risk either where failure of the human action will directly cause an accident or will allow an accident sequence to progress.

3.7 Where a **critical human factor** attribute is assigned, the human action (or critical task) should be clearly defined in the risk control measure.

3.8 **Auditable** or **Not Auditable** reflects whether the risk control measure can be audited or not.

3.9 **Quantitative** or **Qualitative** reflects whether the risk control measure has been based on a quantitative or qualitative assessment of risk.

3.10 **Established** or **Novel** reflects whether the risk control measure is an extension to existing marine technology or operations, whereas novel is where the measure is new. Different grades are possible, for example the measure may be novel to shipping but established in other industries or it is novel to both shipping and other industries.

3.11 **Developed** or **Non-developed** reflects whether the technology underlying the risk control measure is developed both in its technical effectiveness and its basic cost. **Non-developed** is either where the technology is not developed but it can be reasonably expected to develop, or its basic cost can be expected to reduce in a given timescale. The purpose of considering this attribute is to attempt to anticipate development and produce forward looking measures and options.

~~ANNEX 2~~ APPENDIX 9

STANDARD FORMAT FOR REPORTING ~~TRIAL~~ AN APPLICATION~~S~~ OF THE FORMAL SAFETY ASSESSMENT

Introduction

1. This standard format is intended to facilitate the compilation of the results of trial applications according to the "~~Interim~~ Guidelines for the Application of Formal Safety Assessment (FSA) to the IMO Rule-Making Process" and the consistent presentation of those results to IMO.

2. Interested parties having carried out ~~a trial~~ an FSA application ~~of the Interim Guidelines~~ should provide the most significant results ~~of the FSA process~~ in a clear and concise ~~report~~ manner, which can also be understood by other parties not having the same experience in the application of risk assessment techniques.

3. The report of an FSA application should contain an executive summary and the following sections: definition of the problem, background information, method of work, description of the results achieved in each step and final recommendations arising from the FSA ~~process~~ study.

4. The level of detail of the report depends on the problem under consideration. However, to facilitate the understanding and use of the results of the ~~trial~~ FSA application, the report should not exceed 20 pages, excluding figures and appendices.

5. Those submitting the results of the FSA ~~trial~~ application should provide the other interested parties with timely and open access to relevant supporting documentation and source of information or data which are referred to in the above-mentioned report, as reflected in paragraph 9.2 of the ~~Interim~~ FSA Guidelines.

6. The following paragraph presents the standard format of FSA ~~trial~~ application reports. The subjects expected to be presented in each section of the report are listed in italic characters and reference is given, in brackets, to the relevant paragraph(s) of the ~~Interim~~ FSA Guidelines.

STANDARD REPORTING FORMAT

(ref. MSC/MEPC circular)

1. TITLE OF THE TRIAL APPLICATION

2. SUMMARY (MAX 1/2 PAGE)

2.1 Executive summary : scope of the ~~trial~~ application and reference to the paragraph defining the problem assessed and its boundaries.

2.2 Actions to be taken : type of action requested (e.g. for information or review) and summary of the final recommendations listed in section 7.

2.3 Related documents : reference to any supporting documentation.

3. DEFINITION OF THE PROBLEM (MAX 1 PAGE)

3.1 Definition of the problem to be assessed in relation to the proposal under consideration by the decision-makers.

3.2 Reference to the regulation(s) affected by the proposal to be reviewed or developed (in an annex).

3.3 Definition of the generic model (e.g. functions, features, characteristics or attributes which are relevant to the problem under consideration, common to all ships of the type affected by the proposal).

(ref. paragraphs 3.2 and 3.3 of the ~~Interim~~ FSA Guidelines)

4. BACKGROUND INFORMATION (MAX 3 PAGES)

4.1 Lessons learned from recently introduced measures to address similar problems.

4.2 Casualty statistics concerning the problem under consideration (e.g. ship types or accident category).

4.3 Any other sources of data and relevant limitations.

(ref. paragraph 3.4 of the ~~Interim~~ FSA Guidelines)

5. METHOD OF WORK (MAX 3 PAGES)

5.1 Composition and level of expertise of those having carried out the trial application (name and credentials in an annex).

5.2 Description on how the assessment has been conducted in terms of number of meetings, organisation of working groups, etc

5.3 Start and finish date of the assessment.

(ref. paragraph 3.1.2 of the ~~Interim~~ FSA Guidelines)

6 DESCRIPTION OF THE RESULTS ACHIEVED IN EACH STEP
(MAX 10 PAGES)

6.1 For each step, describe:

.1 method and techniques used to carry out the assessment;

.2 assumptions or limitations, if any, and the basis for them; and

.3 outcomes of each step of the FSA methodology, including:

STEP 1 - HAZARD IDENTIFICATION : (ref. paragraph 4.5 of the ~~Interim~~ FSA Guidelines)

- *prioritised list of hazards.*
- *identified significant accident scenarios.*

STEP 2 - RISK ASSESSMENT : (ref. paragraph 5.4 of the ~~Interim~~ FSA Guidelines)

- *types of risk (e.g. individual, societal, environmental, business).*
- *presentation of the distribution of risks depending on the problem under consideration.*
- *identified significant risks*
- *principal influences that affect the risks.*
- *sources of accident and reliability statistics.*

STEP 3 - RISK CONTROL OPTIONS : (ref. paragraph 6.5 of the ~~Interim~~ FSA Guidelines)

- *what hazards are covered by current regulations.*
- *identified risk control options.*
- *assessment of the control options as a function of their effectiveness against risk reduction.*

STEP 4 - COST BENEFIT ASSESSMENT : (ref. paragraph 7.3 of the ~~Interim~~ FSA Guidelines)

- *identified types of cost and benefits involved for each risk control option.*
- *cost-benefit assessment for the entities which are influenced by each option.*
- *identification of the cost effectiveness expressed in terms of cost per unit risk reduction.*

STEP 5 - RECOMMENDATIONS FOR DECISION-MAKING

(ref. paragraph 8.2 of the ~~Interim~~ FSA Guidelines)

- *objective comparison of alternative options.*

- *discussion on how recommendations could be implemented by decision makers.*

7 FINAL RECOMMENDATIONS FOR DECISION MAKING (MAX 2 1/2 PAGES)

7.1 List of final recommendations, ranked and justified in an auditable and traceable manner.

(ref. paragraph 8.2 of the ~~Interim~~ FSA Guidelines)

END OF THE REPORT

IT IS RECOMMENDED THAT THE LENGTH OF THE REPORT BE KEPT TO LESS THAN 20 PAGES EXCLUDING FIGURES AND ANNEXES.

ANNEXES (AS NECESSARY)

.1 name and credential of the experts involved in the trial application

.2 list of references

.3 sources of data

.4 accident statistics

.5 technical support material

.6 any further information

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ANNEX 8

DRAFT TERMS OF REFERENCE FOR AN INTERSESSIONAL CORRESPONDENCE GROUP ON THE FORMAL SAFETY ASSESSMENT

1. To develop further improvements to the Interim Guidelines for the Application of Formal Safety Assessment (FSA) to the IMO rule-making process ((MSC/Circ.829 & MEPC/Circ.335) taking into account the proposals set out in document MSC 72/WP.7, annex 7.

2. To develop further guidance on the use of regulatory impact diagrams (RID) and provide relevant examples of their application.

3. To consider the possible application of risk evaluation criteria taking into account proposals in the document MSC 72/16.

4. To consider the integration of the Human Element into the FSA process.

5. To consider any further proposals arising from the trial applications of the FSA Interim Guidelines, *inter alia,* the studies on bulk carrier safety being developed by the International Collaborative Formal Safety Assessment Study co-ordinated by the United Kingdom (MSC 72/INF.18 and MSC 72/4/3) and by Japan.

6. To submit its report to the Committee at its seventy-fourth session.

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